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U.S. ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND

ECBC-SP-019

MARKET SURVEY: BIOLOGICAL DETECTORS

GUIDE FOR SELECTION OF DETECTION DEVICES AND SYSTEMS

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FOR CHEMICAL AND BIOLOGICAL DEFENSE

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14. ABSTRACT

Detection of biological warfare agents currently relies upon either PCR and immunoassay-based methods or the combination of both. There is a wide array of PCR and immunoassay technologies available to today's scientists. Products are typically designed for a specific application, whether it is for environmental detection or diagnosis. In this report, information pertaining to the use and performance of several leading PCR and immunoassay technologies was collected and evaluated. Several new or alternative methods were also evaluated. The effectiveness of these detection devices was evaluated for the following scenarios: field use, mobile laboratory use, diagnostic laboratory use, and analytical laboratory use. The evaluation criteria for each of these scenarios were based upon expert opinion.

15. SUBJECT TERMS

Field use	Mobile laboratory	Immunoassay-based detection
Detection	Diagnostic laboratory	Nucleic acid/PCR-based detection
Decision analysis	Analytical laboratory	

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EXECUTIVE SUMMARY

In this report, information pertaining to the use and performance of several leading PCR and immunoassay technologies was collected and evaluated. Several new or alternative methods were also evaluated. The effectiveness of these detection devices was evaluated for four different scenarios: field use, mobile laboratory use, diagnostic laboratory use, and analytical laboratory use. The evaluation criteria for each of these scenarios were based upon expert opinion.

Detection devices intended for field use were evaluated based upon their total agents that can be detected, maturity, size, set up time, time to detection, and maintainability of the device or system. Technologies that evaluated well in this scenario included small, versatile detection cartridges, as well as several handheld PCR devices. Devices or systems that did not fare well in the evaluation often required several additional pieces of equipment for use (e.g., centrifuges, water baths, vortexes), which decreased the ease of use and increased the number of manual steps required for operation. Also, the larger the sized devices or systems did not fare well in this scenario.

Detection devices intended for mobile laboratory use were evaluated based upon their ability to detect bacteria, toxins and total agents, operational conditions, size and reusability. Technologies that evaluated well in this scenario included reasonably sized, sensitive detection devices that can detect many agents. Devices that did not fare well in the evaluation often required several manual steps, and manpower requirements, while reducing the ease of use.

Detection devices intended for diagnostic laboratory use were evaluated based upon their utility, total agents that can be detected, time to detection, ease of use, and sensitivity. Technologies that evaluated well in this scenario included fast and effective detection devices based upon PCR technology for clinical samples. Systems and devices that did not fare as well in the evaluation ofter took a long time to detect, did not have a high level of sensitivity, or had to use many consumables.

Detection devices intended for analytical laboratory use were evaluated based upon their ability to obtain a high sensitivity, utility, volume of sample needed, total agents that can be detected, and the ability to multiplex. Detection devices or systems that did well in this scenario included the PCR focused technologies and those systems that used automated technologies that combined PCR and immunoassay. Systems and devices that did not fare as well in this evaluation were generally those that did not have a high sensitivity or were unable to multiplex.

Foreword

The Department of Defense (DoD) is concerned about the proliferation of biological warfare agents and the nation's ability to detect and diagnose the potential exposure of US troops or an attack on the homeland. Therefore, periodic technology reviews and evaluations are coordinated by the Critical Reagents Program (CRP) and the Edgewood Chemical Biological Center (ECBC) to assist the biological defense community. Presented here are assessments of the technologies available for biological agent detection, including PCR- and immunoassay-based technologies as well as a few emerging technologies. This market survey assesses these technologies within a variety of settings, including analytical laboratories, medical diagnostic laboratories, mobile laboratories, and field use. It is the aim of this guide to assist technology managers and research scientists in the field of biological agent detection.

This guide includes information to assist research scientists and the scientific and technology community to select or track detection technologies that meet their varied applications. It includes a thorough market survey of detection devices or systems available, current through May 2004. Brief technical discussions that consider the principles of operation and technological basis of several pieces of equipment are presented. Although Appendix II contains technical information provided by the vendor for each product, it is considered supplementary. Readers that find this information too lengthy may bypass the Appendix with no effect on their overall understanding of the evaluation. For readers who desire more technical information, a point of contact from the manufacturer and company websites are listed with each product.

This guide describes detection devices or systems for detecting biological warfare agents important to the biodefense community. It mainly focuses on PCR and immunoassay based technologies, but does include other technologies in various stages of development. Please refer to Appendix I for an overview of the detection devices and systems evaluated, the technologies available, and the maturity of each device or system presented.

Reference herein to any specific commercial products, processes, or services by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, or recommendation by the United States Government. The information and statements contained in this guide shall not be used for the purpose of advertising, or to imply the endorsement or recommendation of the United States Government. With respect to the information provided in this guide, neither the United States Government nor any of its employees make any warranty, expressed or implied, including but not limited to the warranties of merchantability and fitness for a particular purpose. Further, neither the United States Government nor any of its employees assume any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed.

The information in this guide on specific equipment and technologies has been obtained through literature, web searches and market surveys. Technical comments, suggestions, and product updates are encourage from interested parties. They may be addressed to the Edgewood Chemical Biological Center, 5183 Blackhawk Road, E3330 Room 185, Aberdeen Proving Ground, MD 21010. It is anticipated that this guide will be updated periodically. Questions pertaining to the specific products included in this document should be directed to the manufacturer. Contact information for each evaluated equipment item is included in this report.

Authors' Letter

Dear Reader:

We had updated our 2003 market survey on biological detectors to help inform and update the research and scientific community on current and future detectors for biological threat agents. Many of the detection devices and systems evaluated in this survey use PCR and/or immunoassay technology, but other technologies were also included. We evaluated products that are commercially available and some emerging technologies of interest. There are four different scenarios considered within this document and each has a customized weighting mechanism which refelcts the needs of detection systems for that situation. We gathered the product information by sending out a questionnaire to manufacturers and then ranking each answer.

We would like to suggest the following methodology for using this guide. First, review the scenarios in Section 7; choose one of interest to you and note how the devices or systems ranked for that scenario. Second, take note of the portion the product ranked within and then look at the raw score. Remember that scores have a subjective component and that all the technologies are included in the ranking so don't go by the raw score only Next, go to Appendix II and look up the product name for detailed information on the product. Finally, contact the manufacturer for more information or visit their website.

Appendix I is a quick reference guide to each product in the survey. The name of each product is color coded by technology to make it easier to find a product that may interest you. Appendix II, which includes the product information, is alphabetized to make it easier to find a product of interest. Appendix I also includes a maturity gauge so you can quickly tell if the product is commercially available or not. We hope that you find this survey both helpful and interesting. If you have any comments or suggestions, please contact us.

Sincerely,

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Instructions for the Use of This Guide

This report is useful in the selection of a PCR or immunoassay based technology for detection of biological, viral, and toxin targets. For the purpose of this report, evaluation models, used to generate the ordered lists of technologies, were created. These evaluation models are useful in evaluating emerging technologies and new products for the four scenarios discussed.

This report should be used as a guide and the information of each product was provided by the manufacturer and assumed to be correct. When evaluating products based on the scenario, observe the score in generalized blocks. Scoring summaries have been used to break analyzed technologies into sections to help. Do not judge the product based solely on the raw score. Since there is so much information provided in this report, the authors have also included defined icons for the viewer in Appendix II. The red arrow highlights items of interest about the product, both good and bad. The blue eye indicates technologies to watch in the future. The smiley face indicates that the technology is in widespread use. The green dollar sign indicates that the manufacturer of the products seeks investments.

Appendix I is a quick guide to the products that were evaluated in this survey. The names of the products are color coded according to the technology they utilize. There also is a maturity gauge that indicates that (1) the device or system is commercially available and meets military specification, (2) the device or system is commercially available, (3) a few devices exist, or (4) only one incomplete device exists or only a concept on paper exists.

Appendix II is an alphabetized product information sheet with detailed information on each product evaluated in the survey. Further information on a product of interest can be obtained by contacting the manufacturer or visiting their website, if provided.

PREFACE

This work was started in May 2004 and completed in March 2005.

The use of either trade or manufacturers' names in this report does not constitute an official endorsement of any commercial products. This report may not be cited for purposes of advertisement.

This report has been approved for public release. Registered users should request additional copies from the Defense Technical Information Center; unregistered users should direct such requests to the National Technical Information Service.

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MARKET SURVEY: BIOLOGICAL DETECTORS

Guide for Selection of Detection Devices and Systems

1. Introduction

The purpose of this document is to provide the science and technology community and the research and development scientist with information to aid them in the pursuit of biological assay and detection technology development. This report reviews vendor-supplied information about detection devices or systems that are currently used in biological research and in biodetection assays. Also included in the report are several immature devices or systems that have potential use in biological research and in biodetection assays.

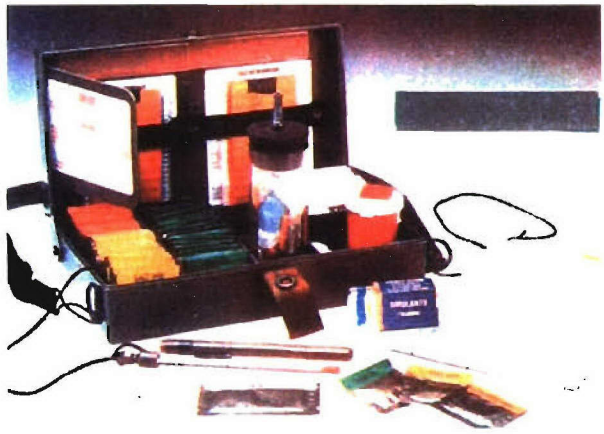
This document is divided into eight sections and includes two appendices. **Section 2** presents a description of the four scenarios that address detection devices or systems needs. **Section 3** provides an overview of PCR based detection technologies. **Section 4** provides an overview of immunoassay based detection technologies. **Section 5** is a brief introduction to the decision analysis process used in the evaluation. **Section 6** discusses the selection factors that were used to compare and evaluate the different detection devices or systems. **Section 7** presents an evaluation of detection devices or systems and general recommendations pertaining to the four different scenarios. **Section 8** concludes with a concise summary of the current state of biological agent detection devices or systems. **Appendix I** is a quick reference table that divides the products by technology and also indicates the maturity level of the product. **Appendix II** describes individual products that were evaluated in this guide.

2. Four Different Scenarios Where Detection Devices or Systems Are Needed

Several fundamentally different methods for detecting biological agents have been or are being developed. However, in different operational environments, one device or system may be preferred over others based on situational circumstances. In the following scenarios, four distinctly different environments demonstrate how different situations can require different devices or systems for biological agent detection.

FIELD SCENARIO

Field use detection devices or systems are typically used by the soldiers or researchers conducting research outside of a typical laboratory setting. These devices or systems would be used outdoors in a variety of environments (e.g., desert, forest, plains, urban) and be subjected to various environmental conditions (e.g., heat, cold, humidity). They need to be small, lightweight, and easy to carry. They should be simple to operate and should not require other machinery such as centrifuges or heat blocks to operate. Kits or devices with limited electrical requirements are preferred. These devices can be disposable with a single use only, or they can be reusable with minimal cleaning required for re-use. Signature is important in the operation of these devices or systems, as large ventilation systems or protective gear could jeopardize covert operations. Field use devices can have a narrow detection of agents range, (e.g., can be specific for one particular target) because several different devices may be deployed on a mission.

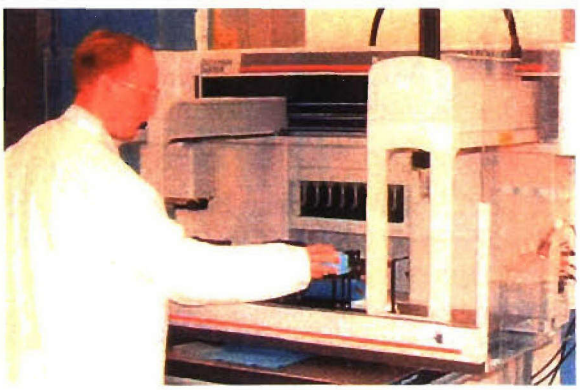


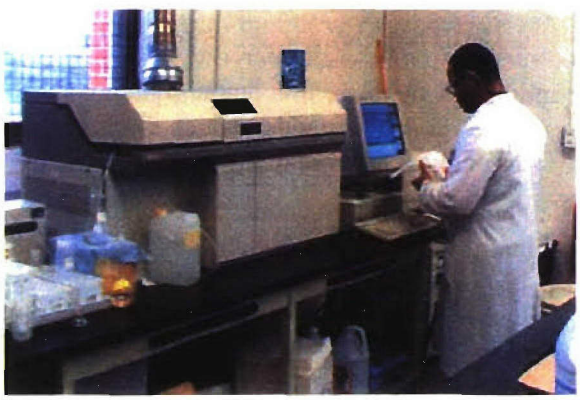
MOBILE LABORATORY SCENARIO

Mobile laboratory detection devices or systems are located in deployable laboratories. They would likely be semi-automated or integrated into a system that is capable of a higher throughput of samples (20-30 samples at a time). Some additional equipment such as centrifuges and vortexes can be used during operation, although smaller systems are preferred. Size is a concern with mobile laboratory components as space is limited and because the detection device or system is likely only one component of the laboratory. A mobile laboratory would ideally be able to operate for a longer period of time than a field use item, indicating that consumables and manpower are a concern. Signature is somewhat important for the mobile laboratory, as extensive safety precautions could hinder the mobility and camouflage of the mobile laboratory. The mobile laboratory detection device or system should ideally be able to detect every biological warfare agent of concern.

DIAGNOSTIC LABORATORY SCENARIO

Diagnostic laboratory detection devices or systems are typically located in a hospital or a similar medical setting. They would be fully automated devices capable of high throughput of samples. The device or system must be able to detect agents from blood, tissue, cultured cells, and other typical samples. An ideal detection device would detect agents very quickly, detect a large variety of agents, have a high level of sensitivity and be easy to operate. This type of device would be used in a hospital setting where size, signature, additional equipment and electrical requirements are of less concern. Calibration and accuracy are critical factors in a medical environment. The device should be easily maintainable with regularly scheduled maintenance, and be relatively easy for a medical staff to operate.





ANALYTICAL LABORATORY SCENARIO

The forensic analytical laboratory scenario is typically a fixed site location that processes samples with the highest scrutiny, and validates previous assays. Analytical laboratory detection devices or systems would be concerned with looking for the greatest amount of recovery possible. This would be very important when trying to detect biological agents from small dilute samples. There are no real concerns with logistical or operational concerns, as issues such as size, weight, signature, transportation, additional equipment and consumables. Ideally, the analytical laboratory detection device or system must be able to detect biological agents from all encountered samples with a consistently high level of effectiveness and sensitivity. The ideal system or device would also be able to multiplex, detect multiple agents within the same sample.

3. Overview of PCR Techniques

Polymerase chain reaction (PCR) refers to a highly sensitive technique by which minute quantities of specific DNA or RNA sequences can be enzymatically amplified to the extent that a sufficient quantity of material is available to reach a threshold "signal" for detection. The impetus for development of this technology grew out of basic research carried out by Mullis, who was awarded the 1993 Nobel Prize for chemistry for PCR, and co-workers and other scientists working at the Cetus Corporation and Department of Human Genetics in Emerysville, California.

The starting material for PCR, the target sequence, is a gene or segment of DNA. The target sequence can be amplified a million fold in a short amount of time. The complementary strands of a double-stranded molecule of DNA are separated by heating. Two small pieces of synthetic DNA, each complementing a specific sequence at one end of the target sequence, serve as primers. Each primer binds to its complementary sequence. Polymerase, a naturally occurring enzyme, starts at each primer and copies the sequence of that strand. Exact replicas of the target sequence have now been produced. In subsequent cycles, double-stranded molecules of both the original DNA and the copies are separated by heating and the primers again bind to the complementary sequences and the polymerase replicates them. After many cycles, there are a great number of small pieces of DNA of the target sequence and this unlimited quantity is then available for further analysis.

The versatility of PCR has been astounding, and it has opened new avenues of research. Applications for PCR include molecular cloning, DNA sequencing, archeology, forensics, amplification of unknown sequences, clinical pathology, genetic diagnosis, characterizing unknown mutations, fingerprinting/population analysis, genome analysis and quantitative PCR of RNA or DNA. It has become a constantly changing tool with further potential in the future.

For further information on PCR, please see the University of California, Berkeley PCR Project website at http://sunsite.berkeley.edu/biotech/pcr/whatisPCR.html or contact the JBAIDS program manager at (703) 681-9600.

4. Overview of Immunoassay Techniques

Immunoassays were first described in the 1950s, although they were not readily applied outside of clinical laboratories until the advent of economical automated plate-reading systems and personal computers to analyze the data. Immunoassays are quick and accurate tests that can be used on-site and in the laboratory to detect specific molecules. Immunoassays rely on the inherent ability of an antibody to bind to the specific structure of a molecule. Antibodies are proteins generated by animals in response to the invasion of a foreign molecule (antigen) into the body. Because antibodies are developed based on the specific three-dimensional structure of an antigen, or analyte, they are highly specific and will bind only to that structure. There are four typical immunoassay formats: monoclonal-polyclonal sandwich, antigen-down, competitive inhibition and rapid.

In a typical microtiter plate sandwich immunoassay, such as the E. coli 0157 Visual Immunoassay (VIA™), a monoclonal antibody is absorbed onto a plastic microtiter plate. The test sample is added to the plate, the antibody on the plate will bind the target antigen, if present and retain it in the plate. Next, a polyclonal antibody is added and will also bind to the antigen, which is now 'sandwich' between the two antibodies. This binding reaction can be measured by radio-isotopes or by enzymes. The radio-isotope or enzyme generates a color signal proportional to the amount of target antigen present. The degree of color can be detected and measured with the naked eye, a scintillation counter, or spectrophotometer depending on the immunoassay format.

In an antigen-down or direct immunoassay, the analyte is coated onto a 96-well microtiter plate and used to bind antibodies found in a sample. When the sample is added, the antigen on the plate it is bound by antibodies from the sample, which are then retained in the well. A species-specific labeled antibody is added which binds to the antibody bound to the antigen on the plate. The higher the signal, the more antibodies there are in the sample.

Competitive inhibition assays are often used to measure small analytes because competitive inhibition assays only require the binding of one antibody. In a sequential competitive inhibition assay format, such as the AflaCup™ Test Kit, a monoclonal antibody is coated onto a 96-well microtiter plate. When the sample is added, the antibody captures free analyte out of the sample. Next, a known amount of labeled analyte is added. The labeled analyte will then also attempt to bind to the monoclonal antibody absorbed onto the plate, however the labeled analyte is inhibited from binding to the monoclonal by the presence of previously bound analyte from the sample. The amount of unlabeled analyte in the sample is inversely proportional to the signal generated by the labeled analyte. The classic competitive

inhibition assay format required the simultaneous addition of labeled and unlabeled analyte. Both analytes will then compete for the binding site on the monoclonal capture antibody on the plate. Like the sequential competitive inhibition format, the colored signal is inversely proportional to the concentration of unlabeled target analyte in the sample.

Rapid immunoassay tests use antibodies to react with antigens and can be developed as monoclonal-polyclonal sandwich formats, competitive inhibition formats and antigen-down formats. With a rapid test, the antibody and antigen reagents are bound to porous membranes, which react with positive samples while channeling excess fluids to a non-reactive part of the membrane. There are two common configurations: a lateral flow test, such as the Bio Threat Alert test strips, where the sample is simply placed in a well and the results are read immediately; and a flow through system, which requires placing the sample in a well, washing the well, adding an analyte-colloidal gold conjugate, and reading the results after a few minutes. One sample is tested per strip or cassette.

For further information on immunoassay technology, please refer to http://www.immunochemistry.com or contact the Critical Reagent Program at (410)436-5562.

5. Evaluation Process

Four scenarios of use were selected for the analysis. These scenarios represent distinctly different uses of detection technologies; in essence, each scenario involves different objectives and requirements. Once the objectives and requirements for the four scenarios were clearly defined, the authors generated an evaluation model. The foundation of the model is the evaluation criteria, which represent the important attributes for detection and are intended to differentiate the various types of products. The criteria were structured in the form of a hierarchy, as shown in Figure 1.

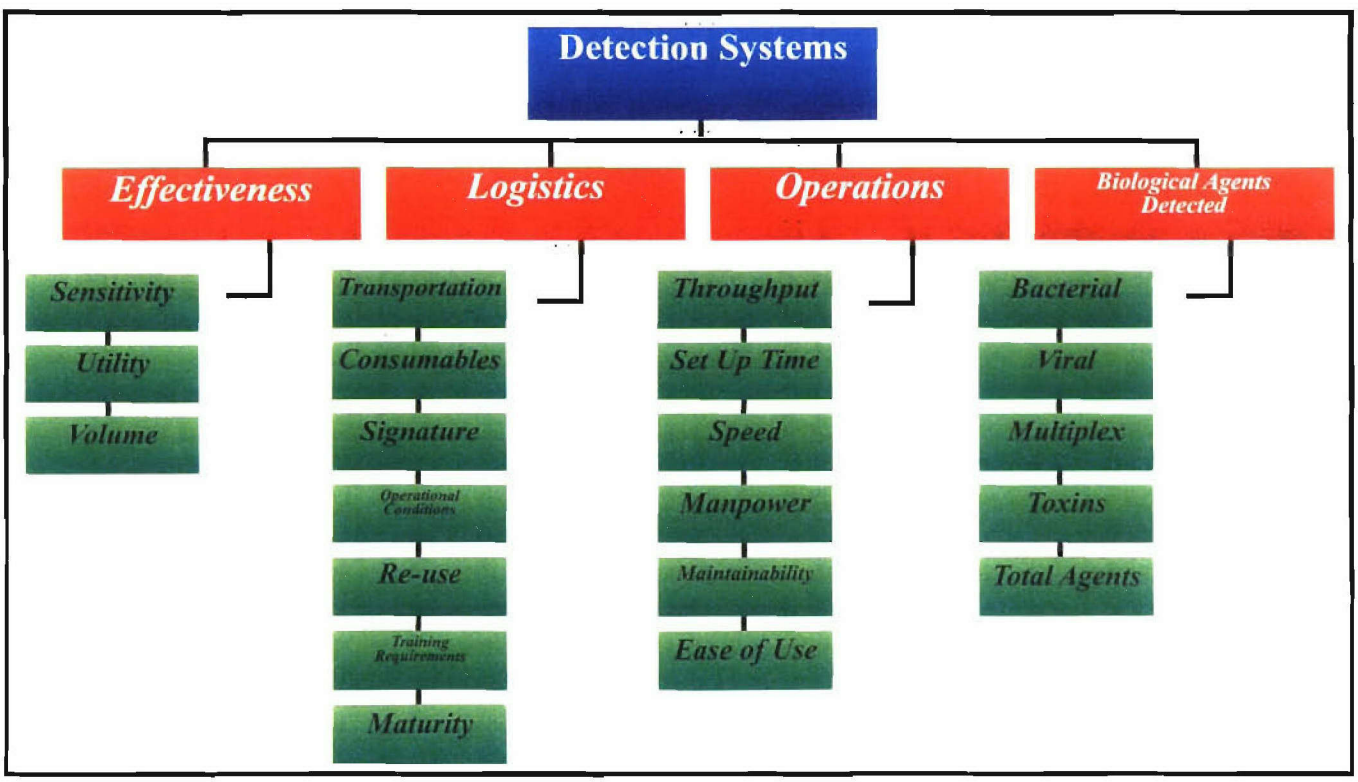


Figure 1. Hierarchical representation of criteria for detection devices or systems product evaluation.

Each evaluation criterion was defined, and then further described with a performance scale. The scales provide a means of measuring how well each product "performs" relative to each criterion. The performance scales can be quantitative (e.g., speed, measured in minutes) or qualitative (e.g., utility, measured by assessing the best fit). Each level on the scale was assigned a utility value, ranging from 0 for the lowest expected performance, to 100 for the highest level of expected performance. Intermediate levels of performance were assigned values between 0 and 100. For this study, products were assessed at discrete scale levels, as opposed to continuous scales. The definitions and performance

scales for the evaluation criteria are shown in Section 6 of this report.

The final step in developing the evaluation model was to weight the criteria. The weights indicate the relative value of a criterion, as defined by its performance scale, compared to the other criteria. The criteria were weighted by distributing 100 points amongst the lowest level criteria for each of the three legs of the hierarchy. Because each scenario is concerned with different objectives and requirements, the criteria weights varied depending on the scenario. Table 1 shows how the weights were distributed relative to the different scenarios.

Table 1. Weighted Performance Criteria Used in the Evaluation Model Determined by Subject Matter Experts

	FIELD USE	MOBILE LAB	DIAGNOSTIC LAB	ANALYTICAL LAB
Sensitivity	7.5	5.0	24.0	30.0
Utility	6.0	5.0	12.0	5.0
Volume	1.5	5.0	4.0	15.0
Transportation	9.0	10.0	2.2	1.0
Consumables	3.0	5.0	2.2	1.0
Signature	1.5	1.0	0.0	1.0
Operational Conditions	3.0	8.0	1.5	1.0
Re-Use	3.0	8.0	1.5	1.0
Training Requirements	1.5	4.0	4.5	2.0
Maturity	9.0	4.0	3.0	3.0
Throughput	4.0	0.8	2.5	2.0
Set Up Time	8.0	0.4	2.5	1.0
Speed	8.0	1.5	10.0	2.0
Manpower	4.0	2.2	1.2	1.0
Maintainability	12.0	5.2	1.2	1.0
Ease of Use	4.0	4.9	7.5	3.0
Bacterial	1.5	6.0	3.0	3.0
Viral	1.5	4.5	3.0	3.0
Multiplex	1.5	1.5	3.0	9.0
Toxins	1.5	6.0	3.0	3.0
Total Agents	9.0	12.0	8.0	12.0

The evaluation criteria were then used to formulate a questionnaire, which was sent to the various manufacturers of detection products. The information provided by the manufacturers was used as the basis for assessing the different products against the evaluation model. The authors also obtained information from subject matter experts working in these particular fields concerning the performance of detection products with which they were familiar. The authors evaluated every product that submitted a completed questionnaire.

Each product was scored relative to each criterion for each scenario. Overall scores and rankings were generated by the decision analysis software Logical Decisions® for Windows (LDW), using a linear additive approach where each criterion score is multiplied by the criterion weight and summed over all the criteria.

The results were analyzed to determine each product's overall effectiveness (utility) for each scenario. These scores were used to identify the best-fit scenario for each technology, as well as determine its potential effectiveness in all four scenarios.

6. Selection Factors

1.0 EFFECTIVENESS GOAL

Ability of the detection system to effectively detect the biological agent from the target source. Taking into consideration the concentration of the biological agent being detected and the amount of sample needed for testing.

1.1 Sensitivity Measure. Ability of detection system to detect the lowest concentration of target agent possible.

100 Detects 1-100 colony forming units (CFUs) per ml
90 Detects 100-1,000 CFUs per ml
75 Detects 1,000-10,000 CFUs per ml
50 Detects 10,000-100,000 CFUs per ml
0 Detects greater than 100,000 CFUs per ml unknown

1.2 Utility Measure. The best setting in which to use the detection device or system.

* Small, lightweight, easy to carry for field use
* Small, lightweight, easy to carry for field use and small, little or no additional equipment and suitable for a mobile or deployable lab
* Small, little or no additional equipment and suitable for a mobile or deployable lab
* Large, relatively easy to use but best suited for a hospital or other diagnostic setting
* Large, relatively easy to use but best suited for a hospital or other diagnostic setting and large, very sensitive and intended for an analytical lab
* Large, very sensitive and intended for an analytical lab

1.3 Volume Measure. The volume of sample needed to effectively detect the target agent with the detection system or device.

100 Less than 10 ul
75 Less than 50 ul
50 Less than 100 ul
25 Less than 250 ul
0 Greater than 250 ul

2.0 LOGISTICS GOAL

Effect of the detection system or device on support and logistical systems.

2.1 Transportation Measure. Ability to transport the detection system or device. Takes into consideration the portability of the system, as well as the weight and volume of the device or system.

* Approximately the size of a soda can
* Approximately the size of a toaster
* Approximately the size of a carry-on luggage suitcase
* Approximately the size of a home dishwasher
* Larger than a home dishwasher

*Varies according to the scenario utilized

2.2 Consumable Measure. Requirement of consumables (items that would need to be re-supplied, such as water, fuel, batteries, chemical, power, etc.) that have to be transported to the site for detection.

100	0-1 consumable or expendable
80	2 consumables or expendables
60	3 consumables or expendables
30	4 consumables or expendables
0	5 or more consumables or expendables or unknown

2.3 Signature Measure. Effect of the detection system or device on the signature of covert operations.

100	Less than 200 BTUS generated
50	Between 200-500 BTUS generated
0	Greater than 500 BTUS generated or unknown

2.4 Operational Conditions Measure. Temperature ranges at which the detection device or system can operate with little or no loss of efficacy.

100	Can be used from 4°C to 45°C
95	Can be used from 4°C to 37°C
80	Can be used from 15°C to 37°C
50	Can be used from 25°C to 37°C
0	Can only be used at 25°C or unknown

2.5 Re-use Measure. Ability of device or system to be cleaned and returned to service, or designed for single use only.

*	Device or system is designed for a single use
*	Device or system is intended for multiple detection assays

2.6 Training Requirements Measure. The amount of training required before being able to utilize the detection device or system.

100	Very brief training
80	An afternoon of training
50	A day of training
0	More than a day of training

2.7 Maturity Measure. The availability of the detection device or system commercially.

100	Is commercially available and meets military specifications
90	Is commercially available
30	A few devices or systems exist (brass board)
15	Only one incomplete device or system exist (bread board)
0	Only a concept on paper exist (white board)

3.0 OPERATIONS GOAL

Effect of the detection device or system on detection efforts and operations during usage. Guide for Selection of Detection Devices and Systems 9

*Varies according to the scenario utilized

3.1 Throughput Measure. The throughput of the detection system or device, measured in samples/run and also related to batch size.

100	Can run 384 samples/batch or higher
80	Can run 96 samples/batch or higher
60	Can run 32 samples/batch or higher
20	Can run 2 samples/batch or higher
0	Can only run 1 sample/batch

3.2 Set Up Measure. The amount of time need to start up the detection device or system, including quality assurance procedures.

100	No set-up required
80	Less than 5 minutes
60	5-10 minutes
40	10-20 minutes
0	Greater than 20 minutes

3.3 Speed Measure. Total time required to detection of a single target agent from a single surface wipe in liquid.

100	20 minutes or less
90	Between 20 and 30 minutes
75	Between 30 and 40 minutes
50	Between 40 and 50 minutes
25	Between 50 and 60 minutes
0	Greater than 60 minutes

3.4 Manpower Measure. The potential for automation of the device or system.

100	The system or device is currently fully automated
90	The system or device could easily be adapted into a fully automated system
60	The system or device could be adapted to a fully automated system with some effort
30	The system or device could be adapted to a semi-automated system with some effort
0	The system or approach is not amendable to automation

3.5 Maintainability Measure. The amount of times the detection device or system needs to be serviced.

100	Never needs serviced
90	Needs service less than once a year
60	Needs service once a year
30	Needs service every 6 months
0	Needs service more often than every 6 months or known

3.6 Ease of Use Measure. The complexity and number of steps required to operate the detection device or system.

100	0-2 steps required
80	3-5 steps required
50	6-8 steps required
20	9-12 steps required
0	Greater than 12 steps required or unknown

4.0 BIOLOGICAL AGENTS DETECTED GOAL

Ability of the detection device or system to detect biological agents, such as bacteria or viruses, detect toxins or multiple agents at the same time.

4.1 Bacterial Measure. Number of assays that have been developed to detect bacteria that are important to biodefense.

100	Can detect 4 or more bacterial agents
75	Can detect 3 bacterial agents
50	Can detect 2 bacterial agents
25	Can detect 1 bacterial agent
0	Can not detect any bacterial agents

4.2 Viral Measure. Number of assays that have been developed to detect viruses that are important to biodefense.

100	Can detect 4 or more viral agents
75	Can detect 3 viral agents
50	Can detect 2 viral agents
25	Can detect 1 viral agent
0	Can not detect any viral agents

4.3 Multiplex Measure. Ability to detect multiple biodefense agents or toxins at the same time.

100	Assay available and capable of detecting 4 or more agents or toxins
50	Assay not available, but capable of detecting 4 or more agents or toxins
75	Assay available and capable of detecting 2 or more agents or toxins
50	Assay not available, but capable of detecting 2 or more agents or toxins
0	Not capable of detecting multiple agents or toxins

4.4 Toxins Measure. Number of assays that have been developed to detect toxins that are important to biodefense.

100	Can detect 4 or more toxins
75	Can detect 3 toxins
50	Can detect 2 toxins
25	Can detect 1 toxin
0	Can not detect any toxins

4.5 Total Agents Measure. Total number of biological warfare agents that assays have been developed for and can be detected.

100	Can detect more than 20 total agents
83.3	Can detect 20-16 total agents
66.7	Can detect 15-11 total agents
50	Can detect 10-6 total agents
33.3	Can detect 5-2 total agents
16.7	Can detect only 1 agent
0	Cannot detect any agents

7. Evaluation of Detection Devices or Systems

FIELD USE

In the evaluation of detection equipment for field use, factors pertaining to the simplicity of transportation of the device or system, time for set up, speed to detection, maintainability, maturity and total agents detectable were considered as the most important criteria. An ideal field use device would be small and easily transportable, require few manual steps to operate, easy to maintain and be able to operate at a variety of environmental conditions. Small, easy to use, and versatile detection devices topped the evaluation for field use detection products. The SMART Tickets Bio Threat Alert Test Strips and the RAMP Tickets scored well as field devices for immunoassay technologies and represent the best fit for this scenario.

The RAZOR scored well as field devices for the handheld PCR technologies. This PCR device ranges in size from 1 kg to 5 kg and would likely be transportable via backpack for field use. Systems and devices that did not fare as well in the evaluation often require several additional pieces of equipment (e.g., centrifuges, shaker, vortex) for use, which decreased the ease of use and increased the number of manual steps. Figure 2 highlights the criteria specific to the evaluation of products and technologies for field use.

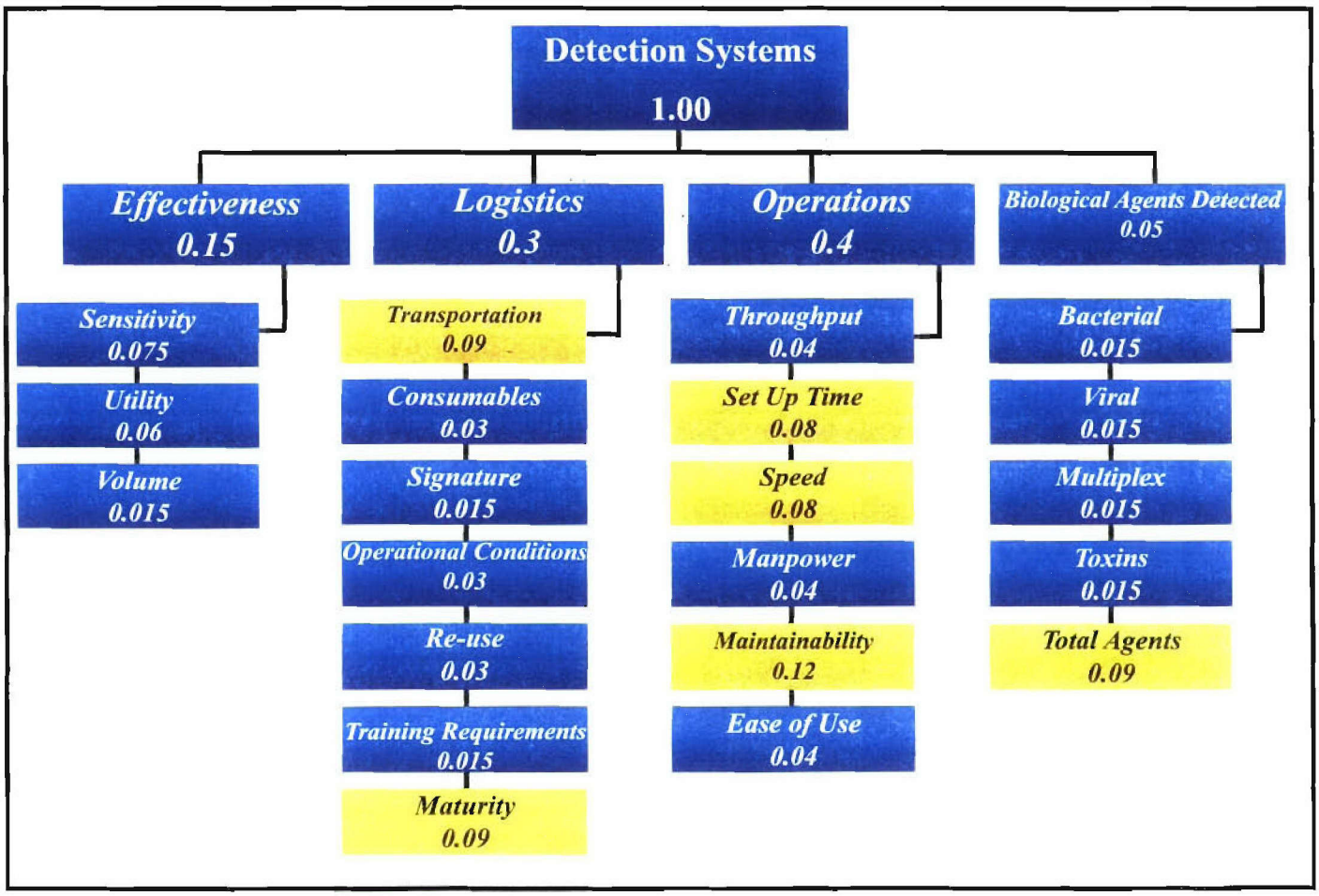


Figure 2. Hierarchical representation of criteria for Evaluation of Detection Products for Field Use

FIELD USE

Top Third

Middle Third

Bottom Third

Ranking for Detection Goal

Alternative	Utility
SMART Tickets (update)	0.864
RAMP (update)	0.824
Bio Threat Alert Test Strips (update)	0.822
PROFILE-1 ATP Lumin. Sys. (update)	0.822
RAZOR (updated)	0.806
Sector PR100 (new)	0.800
NRL Array Biosensor (new)	0.793
Optical Immuno-assay (unchanged)	0.776
Cartridge Reader (new)	0.776
MultiPhoton Detection Portable (unchanged)	0.768
BADD Tickets (update)	0.765
Triage Meter Tickets (update)	0.763
Raptor (update)	0.762
LightCycler PCR (update)	0.760
VIP for EHEC (update)	0.758
NIDS (new)	0.757
M SERIES M1M (new)	0.756
M SERIES M1R (update)	0.752
BDS2 (new)	0.749
Bio-Seeq Thermocycler (update)	0.749
MAR-Magnetic Assay Reader (unchanged)	0.741
Sector Imager 6000 (new)	0.736
HandyLab-EIMB (unchanged)	0.732
ABI PRISM 7900 PCR (unchanged)	0.726
BioMAPP (unchanged)	0.722
BV Detection System (update)	0.722
MultiPhoton Detection Tabletop (unchanged)	0.720
Handheld Fluor. Strip Reader (unchanged)	0.718
CANARY Biosensor (new)	0.715
Anthragen (update)	0.710
ABI PRISM 7000 PCR (unchanged)	0.706
Microfluidic FRET Reader (unchanged)	0.705
UPT Handheld Sensor (unchanged)	0.705
LightTyper (unchanged)	0.700
Handhelp Fluor. Polar. Reader (unchanged)	0.699
Bio-Alloy Smart Material Sensor (new)	0.687
NucliSens EasyQ System (update)	0.687
Rotor-Gene DNA Amp. Sys. (update)	0.687
RAPID Thermocyclers (updated)	0.679
PROFILE-II (unchanged)	0.676
Smart Cycler PCR (update)	0.675
Guardian Reader (update)	0.671
Mini-PCR Fluor. Reader (unchanged)	0.666
iCycler iQ Thermocycler (update)	0.656
Beacon Aflatoxin Plate Kit (updated)	0.654
Bio Detector (BD) (update)	0.650
Assurance EHEC EIA (update)	0.647
M SERIES M384 (update)	0.645
Palm-Cycler PCR (update)	0.644
DNA Engine Thermal Cycler (update)	0.637
Compact, Quantum Dots Biosens. (unchanged)	0.624
PathAlert (new)	0.622
LD 400 Luminescence Detector (update)	0.604
E coli 0157 VIA (update)	0.603
Mx3000P (new)	0.602
ABI PRISM 7300 PCR (new)	0.593
ABI PRISM 7500 PCR (new)	0.584
Staph. Entero. VIA (update)	0.583
BIODET-400 Hand-held (unchanged)	0.582
AD 340 Absorb. Det. (update)	0.581
Lunascan Biodetection Sys. (unchanged)	0.568
Mx 4000 Multiplex PCR Sys. (update)	0.559
Chimera System (unchanged)	0.549
AflaCup Test Kit ELISA (unchanged)	0.547
MatriXarray (unchanged)	0.543
APSIS (new)	0.542
MatriCycler (unchanged)	0.535
ChemSensing (update)	0.534
RIDASCREEN ELISA (unchanged)	0.524
AD 200 Absorb. Det. (new)	0.518
Eppendorf Mastercycler (unchanged)	0.518
DTX 800 Multimode Detector (new)	0.512
DTX 880 Multimode Detector (new)	0.512
Bacillus Diar. Enterotoxin VIA (update)	0.508
Port. NanoChip Workstation (unchanged)	0.503
Threshold System (unchanged)	0.498
ACA-ABS (new)	0.496
Transgenomic WAVE Sys. (unchanged)	0.482
Verigene ID (new)	0.474
BIODET-400 Lab. Instr. (unchanged)	0.474
Invader Assay (unchanged)	0.454
APDS (unchanged)	0.441
Immulite 2000 (new)	0.437
KinExa Bench Top (unchanged)	0.436
Mail Sentry (new)	0.436
ZeptoMARK and SensiChip (new)	0.430
STORM (new)	0.429
NanoChip Workstation (update)	0.423
KinExA 3000 (unchanged)	0.422
CANARY Bioaerosol Sensor (new)	0.407
Mobile Molecular Lab. (unchanged)	0.397
ABCDS-Sentry (new)	0.356
Luminex 100 (update)	0.343
KinExA Handheld (unchanged)	0.328
MAGIChip (unchanged)	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

MOBILE LABORATORY

In the evaluation of detection equipment for mobile laboratories, factors pertaining to the bacterial, total agents and toxins detectable, transportation, operational conditions and re-use ability were considered as the most important criteria. An ideal mobile laboratory device would require few manual steps to operate, require no or little additional equipment, and would have increased throughput, speed, and potential for automation.

Easy transportation and the ability of a device to detect many agents topped the evaluation for mobile laboratory detection products. The ABI PRISM 7900 Sequence Detection System was the highest ranked PCR device. Combining a less than once a year service requirement and ability to detect 25 agents, this system represents the best fit for this scenario. The SMART Tickets were the highest ranked immunoassay devices with no service required and ability to detect 14 agents currently, with others in development. Systems and devices that did not fare as well in the evaluation often required several manual steps for detection, which increased the process time and manpower requirements and reduced the ease of use. Figure 3 highlights the criteria specific to the evaluation of products and technologies for mobile laboratory use.

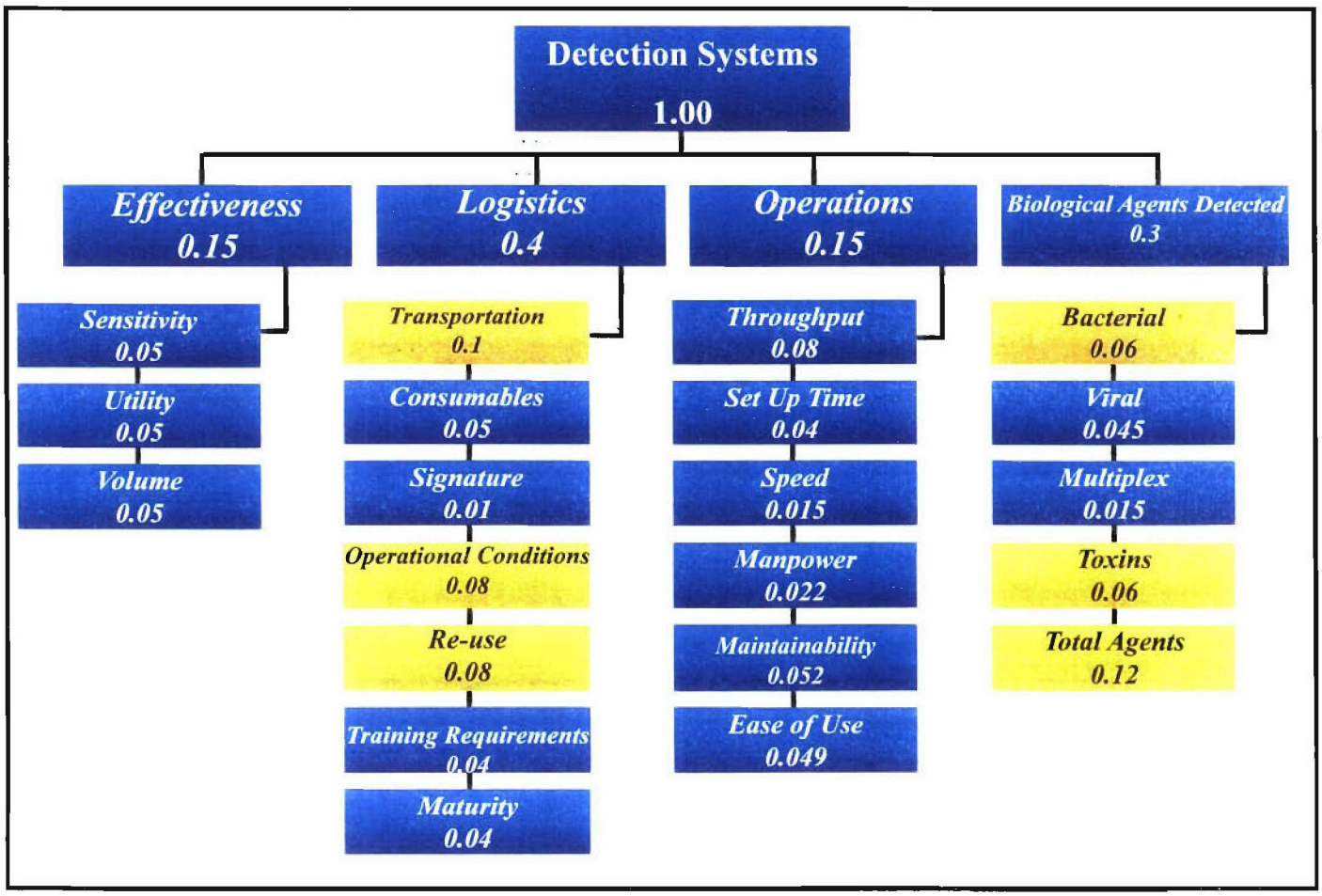


Figure 3. Hierarchical representation of criteria for Evaluation of Detection Products for Mobile Laboratories

MOBILE LABORATORY

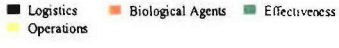
Ranking for Detection Goal

Top Third

Middle Third

Bottom Third

Alternative	Utility
SMART Tickets (update)	0.848
M SERIES M1M (new)	0.787
M SERIES M1R (update)	0.775
Bio Threat Alert Test Strips (update)	0.762
Cartridge Reader (new)	0.760
NRL Array Biosensor (new)	0.757
BioMAPP (unchanged)	0.753
ABI PRISM 7900 PCR (unchanged)	0.751
PROFILE-1 ATP Lumin. Sys. (update)	0.746
BADD Tickets (update)	0.742
HandyLab-EIMB (unchanged)	0.741
BV Detection System (update)	0.737
NIDS (new)	0.734
LightCycler PCR (update)	0.730
BDS2 (new)	0.728
ABI PRISM 7000 PCR (unchanged)	0.728
CANARY Biosensor (new)	0.714
Sector PR100 (new)	0.707
MAR-Magnetic Assay Reader (unchanged)	0.706
RAMP (update)	0.706
RAZOR (updated)	0.700
PROFILE-II (unchanged)	0.687
Raptor (update)	0.682
Bio-Seeq Thermocycler (update)	0.673
Rotor-Gene DNA Amp. Sys. (update)	0.670
Smart Cycler PCR (update)	0.652
Guardian Reader (update)	0.648
MultiPhoton Detection Tabletop (unchanged)	0.647
Anthrigen (update)	0.645
Optical Immuno-assay (unchanged)	0.645
iCycler iQ Thermocycler (update)	0.636
VIP for EHEC (update)	0.635
MultiPhoton Detection Portable (unchanged)	0.632
Sector Imager 6000 (new)	0.631
Triage Meter Tickets (update)	0.619
M SERIES M384 (update)	0.608
DNA Engine Thermal Cycler (update)	0.602
NucliSens EasyQ System (update)	0.601
Bio Detector (BD) (update)	0.601
APDS (unchanged)	0.596
RAPID Thermocyclers (updated)	0.594
Assurance EHEC EIA (update)	0.592
Handheld Fluor. Strip Reader (unchanged)	0.586
UPT Handheld Sensor (unchanged)	0.585
Palm-Cycler PCR (update)	0.581
Beacon Aflatoxin Plate Kit (updated)	0.574
Mini-PCR Fluor. Reader (unchanged)	0.569
Microfluidic FRET Reader (unchanged)	0.563
Staph. Entero. VIA (update)	0.561
PathAlert (new)	0.558
LightTyper (unchanged)	0.557
APSIS (new)	0.550
Bio-Alloy Smart Material Sensor (new)	0.549
ACA-ABS (new)	0.540
Handhelp Fluor. Polar. Reader (unchanged)	0.535
Port. NanoChip Workstation (unchanged)	0.533
E. coli 0157 VIA (update)	0.531
Mx3000P (new)	0.530
Chimera System (unchanged)	0.529
Lunascan Biodetection Sys. (unchanged)	0.526
RIDASCREEN ELISA (unchanged)	0.519
MatriXarray (unchanged)	0.511
ABI PRISM 7300 PCR (new)	0.499
ChemSensing (update)	0.498
MatriCycler (unchanged)	0.486
ABI PRISM 7500 PCR (new)	0.484
Compact, Quantum Dots Biosens. (unchanged)	0.483
BIODET-400 Hand-held (unchanged)	0.483
Bacillus Diar. Enterotoxin VIA (update)	0.480
AD 340 Absorb. Det. (update)	0.474
Eppendorf Mastercycler (unchanged)	0.473
LD 400 Luminescence Detector (update)	0.469
CANARY Bioaerosol Sensor (new)	0.463
AflaCup Test Kit ELISA (unchanged)	0.453
Mx 4000 Multiplex PCR Sys. (update)	0.451
AD 200 Absorb. Det. (new)	0.450
STORM (new)	0.443
Mail Sentry (new)	0.434
NanoChip Workstation (update)	0.431
Mobile Molecular Lab. (unchanged)	0.430
KinExa Bench Top (unchanged)	0.425
DTX 800 Multimode Detector (new)	0.423
DTX 880 Multimode Detector (new)	0.423
Verigene ID (new)	0.417
BIODET-400 Lab. Instr. (unchanged)	0.392
Invader Assay (unchanged)	0.390
ZeptoMARK and SensiChip (new)	0.373
Transgenomic WAVE Sys. (unchanged)	0.372
Luminex 100 (update)	0.372
ABCDS-Sentry (new)	0.352
Threshold System (unchanged)	0.341
Immulite 2000 (new)	0.335
MAGIChip (unchanged)	0.329
KinExA 3000 (unchanged)	0.315
KinExA Handheld (unchanged)	0.298



Preference Set = Mobile Laboratory

DIAGNOSTIC LABORATORY

In the evaluation of detection equipment for diagnostic laboratories, factors pertaining to the sensitivity, utility, time to detection, ease of use, and total agents detectable were considered as the most important criteria. An ideal diagnostic laboratory device would require relatively quick performance and would have high sensitivity requirements.

Effective, fast, and efficient detection devices topped the evaluation for diagnostic laboratory detection devices or systems. The ABI Prism 7900 Detection System was the highest ranked PCR device. Combining high sensitivity and few consumables, this system represents the best fit for this scenario. The Sector Images 6000 and the Sector PR100 scored the highest among the immunoassay detection devices. Systems and devices that did not fare as well in the evaluation were often not sensitive, used many consumables, were slow to detection, and did not detect many agents. Figure 4 highlights the criteria specific to the evaluation of products and technologies for diagnostic laboratory use.

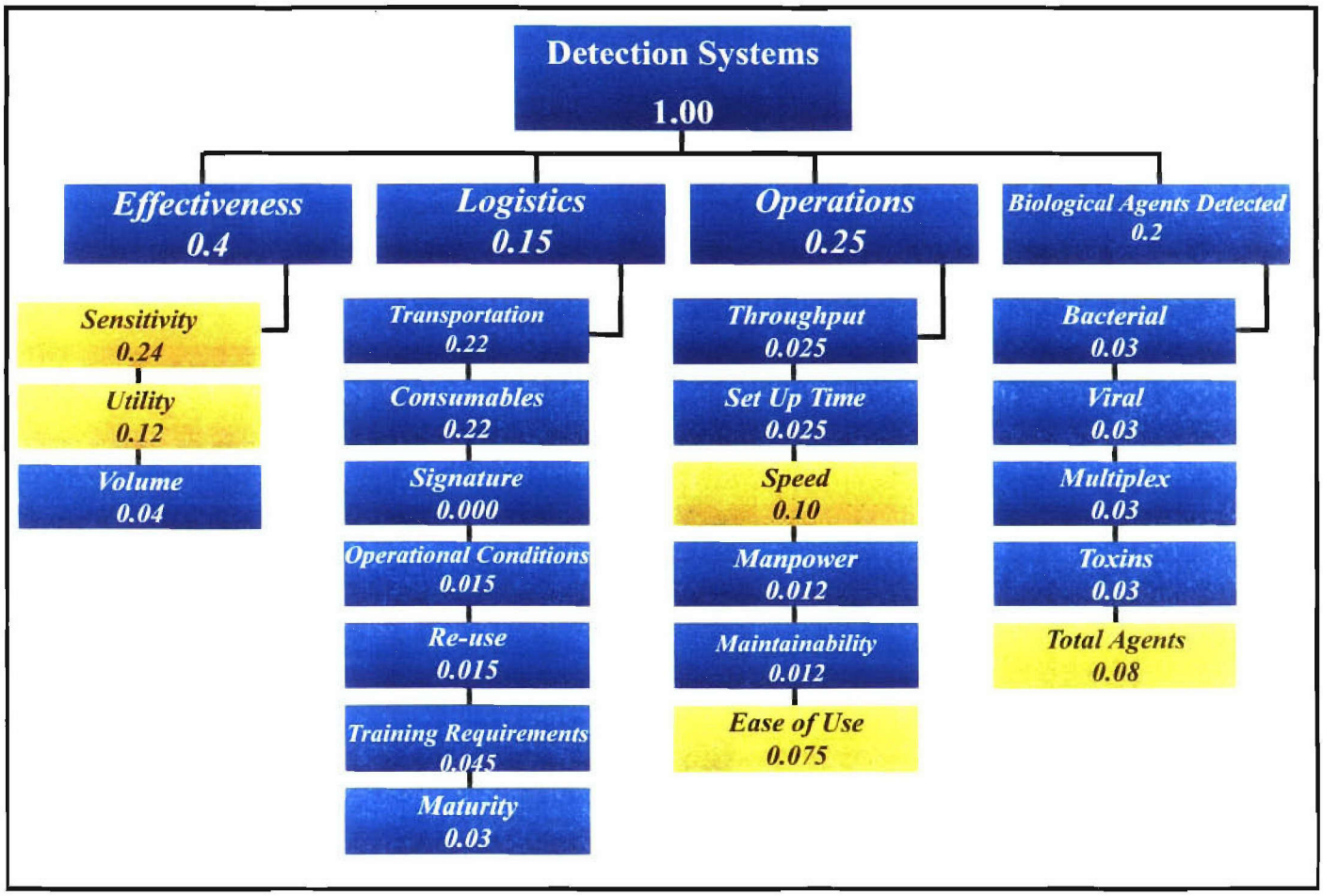


Figure 4. Hierarchical representation of criteria for Evaluation of Detection Products for Diagnostic Laboratories

DIAGNOSTIC LABORATORY

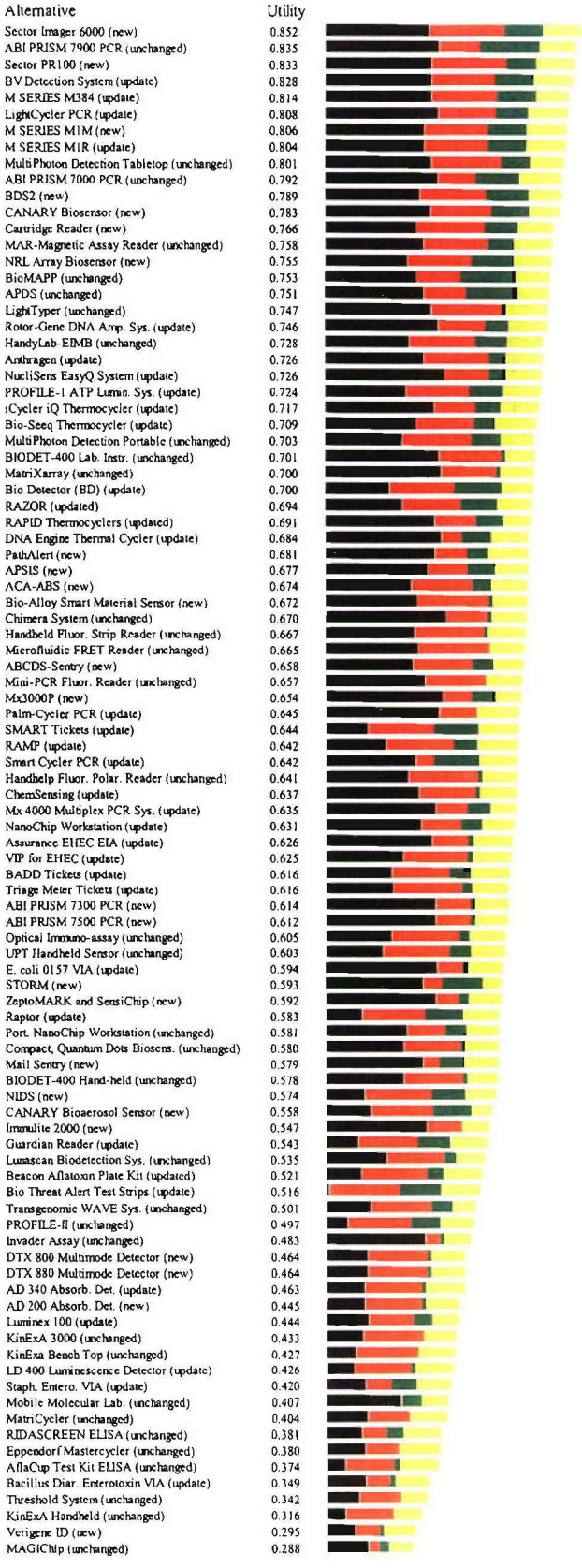
Ranking for Detection Goal

Top Third

Middle Third

Bottom Third

Alternative	Utility
Sector Imager 6000 (new)	0.852
ABI PRISM 7900 PCR (unchanged)	0.835
Sector PR100 (new)	0.833
BV Detection System (update)	0.828
M SERIES M384 (update)	0.814
LightCycler PCR (update)	0.808
M SERIES M1M (new)	0.806
M SERIES M1R (update)	0.804
MultiPhoton Detection Tabletop (unchanged)	0.801
ABI PRISM 7000 PCR (unchanged)	0.792
BDS2 (new)	0.789
CANARY Biosensor (new)	0.783
Cartridge Reader (new)	0.766
MAR-Magnetic Assay Reader (unchanged)	0.758
NRL Array Biosensor (new)	0.755
BioMAPP (unchanged)	0.753
APDS (unchanged)	0.751
LightTyper (unchanged)	0.747
Rotor-Gene DNA Amp. Sys. (update)	0.746
HandyLab-EIMB (unchanged)	0.728
Anthragen (update)	0.726
NucliSens EasyQ System (update)	0.726
PROFILE-1 ATP Lumin. Sys. (update)	0.724
iCycler iQ Thermocycler (update)	0.717
Bio-Seeq Thermocycler (update)	0.709
MultiPhoton Detection Portable (unchanged)	0.703
BIODET-400 Lab. Instr. (unchanged)	0.701
MatriXarray (unchanged)	0.700
Bio Detector (BD) (update)	0.700
RAZOR (updated)	0.694
RAPID Thermocyclers (updated)	0.691
DNA Engine Thermal Cycler (update)	0.684
PathAlert (new)	0.681
APSIS (new)	0.677
ACA-ABS (new)	0.674
Bio-Alloy Smart Material Sensor (new)	0.672
Chimera System (unchanged)	0.670
Handheld Fluor. Strip Reader (unchanged)	0.667
Microfluidic FRET Reader (unchanged)	0.665
ABCDS-Sentry (new)	0.658
Mini-PCR Fluor. Reader (unchanged)	0.657
Mx3000P (new)	0.654
Palm-Cycler PCR (update)	0.645
SMART Tickets (update)	0.644
RAMP (update)	0.642
Smart Cycler PCR (update)	0.642
Handhelp Fluor. Polar. Reader (unchanged)	0.641
ChemSensing (update)	0.637
Mx 4000 Multiplex PCR Sys. (update)	0.635
NanoChip Workstation (update)	0.631
Assurance EHEC EIA (update)	0.626
VIP for EHEC (update)	0.625
BADD Tickets (update)	0.616
Triage Meter Tickets (update)	0.616
ABI PRISM 7300 PCR (new)	0.614
ABI PRISM 7500 PCR (new)	0.612
Optical Immuno-assay (unchanged)	0.605
UPT Handheld Sensor (unchanged)	0.603
E. coli 0157 VIA (update)	0.594
STORM (new)	0.593
ZeptoMARK and SensiChip (new)	0.592
Raptor (update)	0.583
Port. NanoChip Workstation (unchanged)	0.581
Compact, Quantum Dots Biosens. (unchanged)	0.580
Mail Sentry (new)	0.579
BIODET-400 Hand-held (unchanged)	0.578
NIDS (new)	0.574
CANARY Bioaerosol Sensor (new)	0.558
Immulite 2000 (new)	0.547
Guardian Reader (update)	0.543
Lumascan Biodetection Sys. (unchanged)	0.535
Beacon Aflatoxin Plate Kit (updated)	0.521
Bio Threat Alert Test Strips (update)	0.516
Transgenomic WAVE Sys. (unchanged)	0.501
PROFILE-fl (unchanged)	0.497
Invader Assay (unchanged)	0.483
DTX 800 Multimode Detector (new)	0.464
DTX 880 Multimode Detector (new)	0.464
AD 340 Absorb. Det. (update)	0.463
AD 200 Absorb. Det. (new)	0.445
Luminex 100 (update)	0.444
KinExA 3000 (unchanged)	0.433
KinExa Bench Top (unchanged)	0.427
LD 400 Luminescence Detector (update)	0.426
Staph. Entero. VIA (update)	0.420
Mobile Molecular Lab. (unchanged)	0.407
MatriCycler (unchanged)	0.404
RIDASCREEN ELISA (unchanged)	0.381
Eppendorf Mastercycler (unchanged)	0.380
AflaCup Test Kit ELISA (unchanged)	0.374
Bacillus Diar. Enterotoxin VIA (update)	0.349
Threshold System (unchanged)	0.342
KinExA Handheld (unchanged)	0.316
Verigene ID (new)	0.295
MAGiChip (unchanged)	0.288



Effectiveness Operations Biological Agents Logistics

Preference Set = Diagnostic Laboratory

ANALYTICAL LABORATORY

In the evaluation of detection equipment for analytical laboratories, factors pertaining to sensitivity, utility, volume, total agents detected and ability to multiplex were considered to be the most important criteria. An ideal analytical laboratory device would require the generation of a nearly perfect sensitivity, as well as ability to detect many agents in the same sample.

The ABI PRISM 7900 and 7000 Detection systems scored particularly well in the evaluation for analytical laboratory PCR detection products. The ABI PRISM 7900 was the highest ranked device, combining high sensitivity and the ability to detect many agents and multiple agents in the same sample, and represents the best fit for this scenario. Other devices, such as the BioMAPP and APDS systems, use both PCR and immunoassay technologies and scored well in this category due to their high sensitivity and ability to detect multiple agents in a single sample. Most of the immunoassay devices did not fare well for this category due to lack of sensitivity and lack of multiplex capabilities with the exception of the Sector Images 6000. Systems and devices that did not fare as well in the evaluation often had poor sensitivity. Figure 5 highlights the criteria specific to the evaluation of products and technologies for analytical laboratory use.

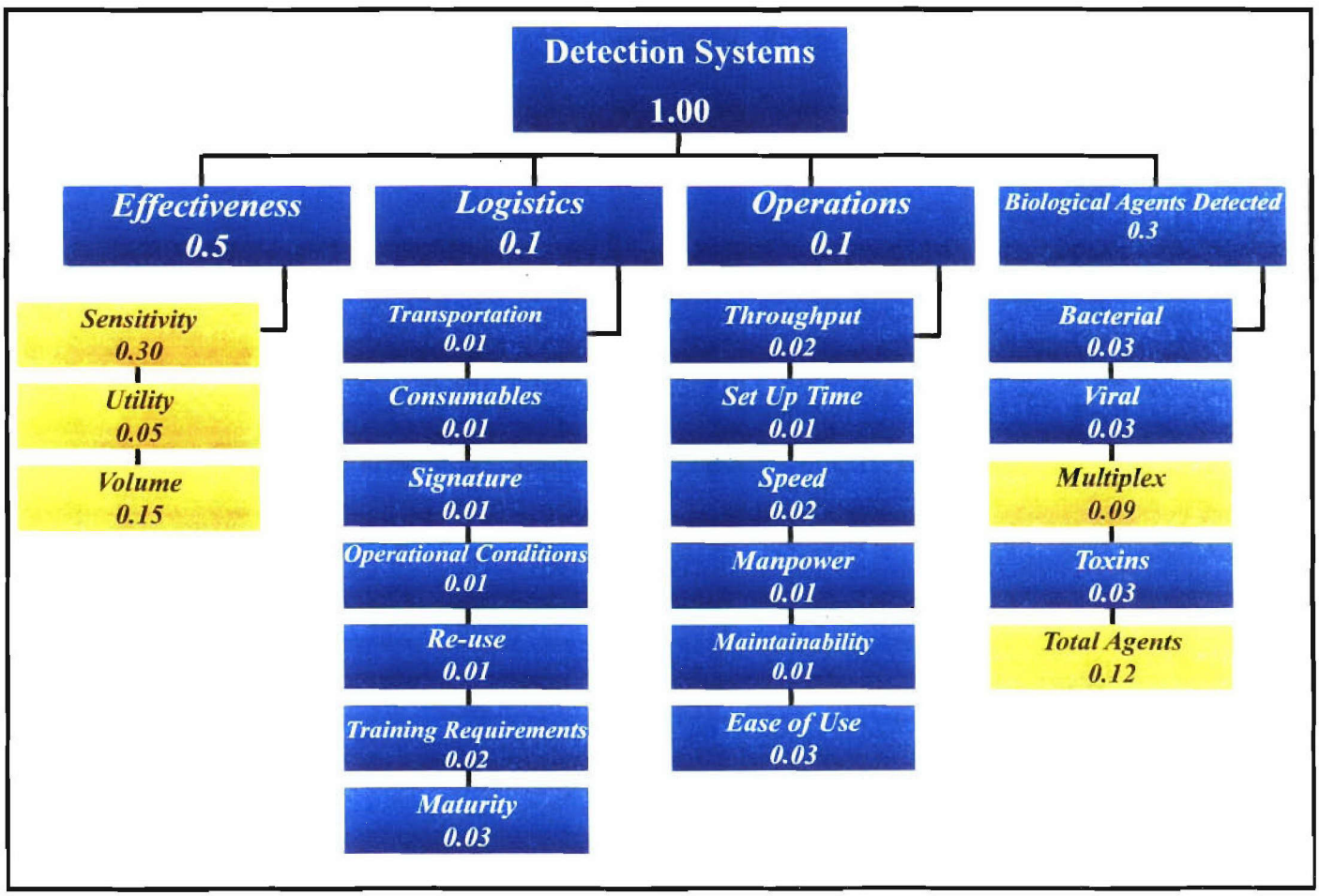


Figure 5. Hierarchical representation of criteria for Evaluation of Detection Products for Analytical Laboratories

ANALYTICAL LABORATORY

Ranking for Detection Goal

Top Third

Middle Third

Bottom Third

Alternative	Utility
ABI PRISM 7900 PCR (unchanged)	0.918
ABI PRISM 7000 PCR (unchanged)	0.866
BioMAPP (unchanged)	0.796
LightCycler PCR (update)	0.794
BDS2 (new)	0.792
CANARY Biosensor (new)	0.787
Sector Imager 6000 (new)	0.786
DNA Engine Thermal Cycler (update)	0.776
HandyLab-EIMB (unchanged)	0.759
APDS (unchanged)	0.752
Rotor-Gene DNA Amp. Sys. (update)	0.749
NucliSens EasyQ System (update)	0.742
MultiPhoton Detection Tabletop (unchanged)	0.736
RAZOR (updated)	0.729
iCycler iQ Thermocycler (update)	0.714
Mx 4000 Multiplex PCR Sys. (update)	0.711
BV Detection System (update)	0.708
MultiPhoton Detection Portable (unchanged)	0.708
M SERIES M384 (update)	0.705
MAR-Magnetic Assay Reader (unchanged)	0.705
APSIS (new)	0.703
PROFILE-1 ATP Lumin. Sys. (update)	0.696
Cartridge Reader (new)	0.696
M SERIES M1M (new)	0.695
Mx3000P (new)	0.694
M SERIES M1R (update)	0.693
Sector PR100 (new)	0.688
PathAlert (new)	0.686
MatriXarray (unchanged)	0.684
Chimera System (unchanged)	0.677
RAPID Thermocyclers (updated)	0.672
Smart Cycler PCR (update)	0.662
Anthragen (update)	0.662
ZeptoMARK and SensiChip (new)	0.661
Bio-Seeq Thermocycler (update)	0.656
NRL Array Biosensor (new)	0.649
NanoChip Workstation (update)	0.639
Palm-Cycler PCR (update)	0.633
Mail Sentry (new)	0.629
STORM (new)	0.625
LightTyper (unchanged)	0.624
ABI PRISM 7300 PCR (new)	0.621
ABI PRISM 7500 PCR (new)	0.620
BIODET-400 Lab. Instr. (unchanged)	0.592
Bio-Alloy Smart Material Sensor (new)	0.587
Assurance EHEC EIA (update)	0.578
Bio Detector (BD) (update)	0.575
Port. NanoChip Workstation (unchanged)	0.573
SMART Tickets (update)	0.567
RAMP (update)	0.563
Mobile Molecular Lab. (unchanged)	0.563
Compact, Quantum Dots Biosens. (unchanged)	0.562
Mini-PCR Fluor. Reader (unchanged)	0.555
VIP for EHEC (update)	0.552
Handheld Fluor. Strip Reader (unchanged)	0.547
BIODET-400 Hand-held (unchanged)	0.547
Triage Meter Tickets (update)	0.546
Microfluidic FRET Reader (unchanged)	0.543
Optical Immuno-assay (unchanged)	0.539
E. coli 0157 VIA (update)	0.537
BADD Tickets (update)	0.533
ACA-ABS (new)	0.533
Invader Assay (unchanged)	0.528
CANARY Bioaerosol Sensor (new)	0.527
ABCDS-Sentry (new)	0.527
UPT Handheld Sensor (unchanged)	0.524
Raptor (update)	0.518
ChemSensing (update)	0.515
NIDS (new)	0.492
Immulite 2000 (new)	0.486
Handhelp Fluor. Polar. Reader (unchanged)	0.469
Transgenomic WAVE Sys. (unchanged)	0.466
Lunascan Biodetection Sys. (unchanged)	0.437
Bio Threat Alert Test Strips (update)	0.425
Beacon Aflatoxin Plate Kit (updated)	0.371
Staph. Entero. VIA (update)	0.370
Guardian Reader (update)	0.345
DTX 800 Multimode Detector (new)	0.344
DTX 880 Multimode Detector (new)	0.344
Luminex 100 (update)	0.342
AD 340 Absorb. Det. (update)	0.336
PROFILE-II (unchanged)	0.319
AD 200 Absorb. Det. (new)	0.318
MAGIChip (unchanged)	0.317
LD 400 Luminescence Detector (update)	0.312
MatriCycler (unchanged)	0.309
RIDASCREEN ELISA (unchanged)	0.299
Eppendorf Mastercycler (unchanged)	0.288
Verigene ID (new)	0.260
Bacillus Diar. Enterotoxin VIA (update)	0.235
KinExA 3000 (unchanged)	0.192
Threshold System (unchanged)	0.179
KinExa Bench Top (unchanged)	0.167
AflaCup Test Kit ELISA (unchanged)	0.163
KinExA Handheld (unchanged)	0.101

Effectiveness Biological Agents Logistics Operations

Preference Set = Analytical Laboratory

8. Summary

The process of comparison and contrast among competing scientific technologies is a useful exercise to assist the research community in deciding which product best fits their particular needs. As a variety of fundamentally different technologies now exist for the task of detection, a method for comparison is particularly useful at this time. Product information was collected from interested vendors and compared with a model, as well as a handful of traditional protocols. A set of important and discriminating criteria was established to differentiate between competing technologies and used to generate overall rankings for four different usage scenarios. The overall ranking weights were based upon the authors' experiences and opinions, and would likely vary slightly from person to person, although they tend to represent the general opinions of the research community at large. The model generated during this report permits sensitivity analysis that could be used to consider other views.

A potentially useful way to use this guide would be to review the research scenario that most relates to an area of interest, identify which products scored well in the evaluation for each technology, and then closely examine these products using the product information contained within Appendix II. When looking at the product score, do not judge the product base solely on the raw score. Look at the product score in blocks (top, middle, bottom); the products were evaluated in blocks of thirds. Information for product representatives is included for each product so that additional information can be obtained. Appendix II is intended as an independent document that can be used as a general guide to present information on several options for detection products.

APPENDIX I

TECHNOLOGY QUICK REFERENCE GUIDE

Technology Quick Reference

	PCR Based Technology	Immunoassay Technology	Both PCR & Imunoassay Technologies	Other Technology: Specify	Maturity Gauge
ABI PRISM 7000 Sequence Detection System	X				●
Automated Bioaerosol Collection and Detection System (ABCDS) Sentry		X			O
ABI 7300 Real Time PCR System	X				◎
ABI 7500 Real Time PCR System	X				◎
ABI PRISM 7900 Sequence Detection System	X				●
Automated Continuous Analysis Array Biosensor (ACA-ABS)		X			O
AD 200 Absorbance Detector		X			O
AD 340 Absorbance Detector		X			◎
AflaCup Test Kit		X			◎
Anthragen		X			⊙
Autonomous Pathogen Detection System (APDS)			X		O
Assurance EHEC EIA		X			◎
APSIS (Assay Processing and Specific Identification System)	X			PCR & Microarray	O
Bacillus Diarrhoeal Enterotoxin Visual Immunoassay (VIA)		X			◎
BADD Tickets		X			●
Biological Detection System – Generation 2 (BDS2)				Optical Sensor	O
Beacon Aflatoxin Plate Kit		X			◎
Bio Detector (BD)		X			●
Bio Threat Alert Tests Strip		X			◎
Bio-Alloy Smart Material Sensor		X			O

Maturity Gauge Key:

Comercially available & meets military specs. ●
Comercially available ◎
A few devices exist ◎
Only one incomplete device exist ⊙
Only a concept on paper O

Technology Quick Reference

	PCR Based Technology	Immunoassay Technology	Both PCR & Imunoassay Technologies	Other Technology: Specify	Maturity Gauge
BIODET 400 Handheld and Laboratory Instruments		X			O
BioMapp			X		O
Bio-Seeq	X				O
BV Detection System		X			O
CANARY Sensors		X		B cell based	O
Cartridge Reader		X			⊙
ChemSensing Colorimetric Sensor				Colorimetric	O
Chimera System	X				O
Compact Quantum Dots Based Biosensor		X			⊙
DNA Engine Thermal Cyclers	X				O
E coli 0157 Visual Immunoassay (VIA)		X			O
DTX 800 Multimode Detector		X			O
DTX 880 Multimode Detector		X			O
Eppendorf Mastercycler	X				●
Guardian Reader		X			O
Handheld Fluorescence Polarization Reader		X			O
Handheld Fluorescence Strip Reader		X			O
HandyLab-EIMB	X				O
icycler iQ	X				O
Immulite 2000		X			O
Invader Assay				Enzymatic	O
KinExa 3000		X			O
KinExA Benchtop		X			O
KinExA Handheld		X			O
LD 400 Luminescence Detector				Photometric	O
LightCycler	X				●
LightTyper	X				O
Luminex 100			X	Flow Cytometry	O
Luminscan Biodetection System		X		Optical Fiber w Fluorescence	⊙

Maturity Gauge Key:

Comercially available & meets military specs. ●
Comercially available O
A few devices exist O
Only one incomplete device exist ⊙
Only a concept on paper ○

Technology Quick Reference

	PCR Based Technology	Immunoassay Technology	Both PCR & Imunoassay Technologies	Other Technology: Specify	Maturity Gauge
M SERIES M1M		X			◉
M SERIES M1R		X			◉
M Series M384		X			◉
MAGIChip			X	Microarray	○
Mail Sentry	X				◉
MAR-Magnetic Assay Reader		X		Mutual Induction	○
MatriCycler	X				○
MatriXarray	X				○
Microfluidic FRET Reader		X			○
Mini-PCR Fluorescence Reader	X				○
Mobile Molecular Lab	X				◉
Multiphoton Detection Portable and Tabletop Versions		X			○
Mx4000 Multiplex Quantitative PCR System	X				◉
Mx3000P Real Time PCR System	X				◉
NanoChip Molecular Biology Workstation				Microarray	◉
NIDS (Nano-Intelligent Detection System) Assay		X			○
NRL Array Biosensor		X			○
NucliSens EasyQ System	X				◉
Optical Immuno-assay		X			◉
Palm-Cycler	X				◉
PathAlert	X				◉
Portable NanoChip Molecular Biology Workstation	X			Microarray	○

Maturity Gauge Key:

Comercially available & meets military specs. ●
Comercially available ◉
A few devices exist ◉
Only one incomplete device exist ⊙
Only a concept on paper ○

Technology Quick Reference

	PCR Based Technology	Immunoassay Technology	Both PCR & Imunoassay Technologies	Other Technology: Specify	Maturity Gauge
PROFILE-1 ATP Luminescence System				Luminescence	●
PROFILE II		X			○
RAMP Tickets		X			●
RAPID	X				●
RAPTOR		X			●
RAZOR	X				○
RIDASCREEN ELISA Test Kits		X			○
Roto-Gene Real Time DNA Amplification System	X				○
Sector Imager 6000		X			○
Sector PR100		X			○
SMART & SMART II Tickets		X			●
Smart Cycler	X				●
Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA)		X			○
STORM (STations Of Robotic Monitoring)			X		○
Threshold System	X				●
Transgenomic WAVE System	X			Liquid chromatography	○
Triage Meter		X			○
Upconverting Phosphor Technology (UPT) Handheld Sensor		X			○
Verigene ID		X		Nanoparticle Probes	○
VIP for EHEC		X			○
ZeptoMARK and SensiChip				Microarray	○

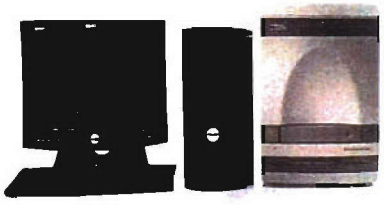
Maturity Gauge Key:

Comercially available & meets military specs. ●
Comercially available ○
A few devices exist ○
Only one incomplete device exist ⊙
Only a concept on paper ○

APPENDIX II
EVALUATION OF DETECTION PRODUCTS

ABI 7300 Real Time PCR System

by Applied Biosystems



Description: The instrument is an integrated system designed to perform both real-time PCR and post-PCR analysis. The instrument is capable of analyzing 96 samples simultaneously in a 96-well plate format. The instrument provides specialized application specific software that collects and analyzes the fluorescence data for the application of absolute quantitation and allelic discrimination/SNP (Single Nucleotide Polymorphism) detection.

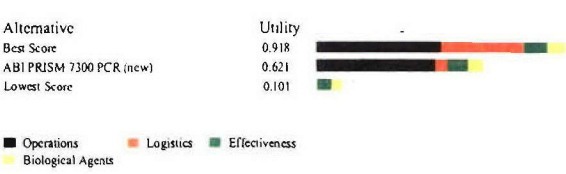
Technology: The instrument support two homogeneous reaction chemistries, the fluorogenic 5' nuclease assay using TaqMan® probes and the SYBR® Green I double stranded DNA binding dye chemistry. The instrument utilizes a tungsten-halogen lamp, a cooled charge coupled device (CCD) camera, and emission filters, to enable multiple wavelength detection. Instrument software utilizes a multicomponenting algorithm to provide precise deconvolution of multiple dye signals, to enable the simultaneous detection of multiple fluorophores with little crosstalk.

Able to Detect the Following Organisms/Toxins:	
Bacillus anthracis (1)	VEE virus (1)
E. coli 0157:H7 (1)	Hanta virus (1)
Francisella tularensis (1)	Yellow fever virus (1)
Vibrio cholera (1)	Dengue fever virus (1)
Corynebacterium diptheria (1)	Ebola viruses (1)
Burkholdera mallei (1)	Orthopox virus (1)
Burkholderia pseudomallei (1)	MS-2 bacteriophage (1)
Yersinia pestis (1)	Botulinum toxins A,B,E (1)
Coxiella burnetti (1)	SEB (1)
Rickettsia prowazekii (1)	Ricin (1)
Brucella species (1)	
Marburg virus (1)	
Rift Valley fever virus (1)	

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
ABI PRISM 7300 PCR (new)	0.621
Lowest Score	0.101



Preference Set = Analytical Laboratory

ABI 7300 System ranked in the middle third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.

Diagnostic Laboratory Ranking

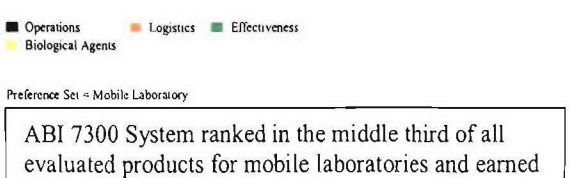
Alternative	Utility
Best Score	0.852
ABI PRISM 7300 PCR (new)	0.614
Lowest Score	0.288

Preference Set = Diagnostic Laboratory

ABI 7300 System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
ABI PRISM 7300 PCR (new)	0.499
Lowest Score	0.298

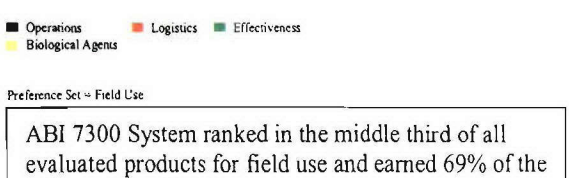


Preference Set = Mobile Laboratory

ABI 7300 System ranked in the middle third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.

Field Use Ranking

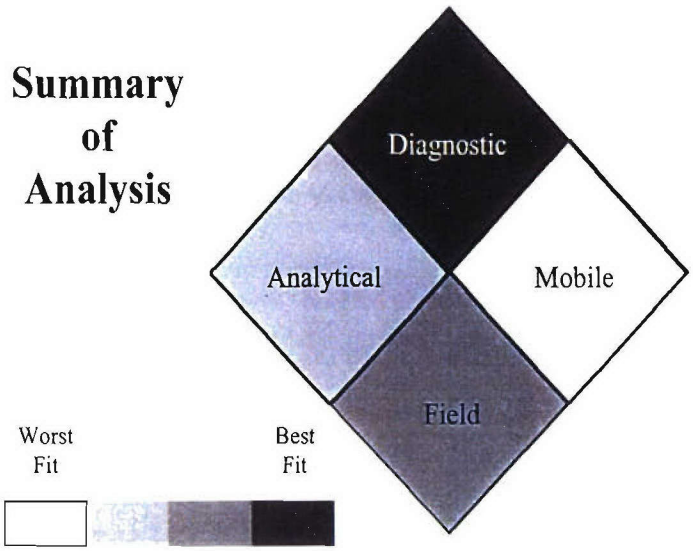
Alternative	Utility
Best Score	0.864
ABI PRISM 7300 PCR (new)	0.593
Lowest Score	0.302



Preference Set = Field Use

ABI 7300 System ranked in the middle third of all evaluated products for field use and earned 69% of the utility points of the best score.

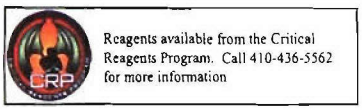
Summary of Analysis



ABI 7300 Real Time PCR System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available



System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 4 consumable or expendable needed
- Once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry on luggage
- Between 25 and 50 kg
- Shelf life measure not applicable

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components must be stored at 4°C
- The performance of the device or system is not influenced by relative humidity

Cost: $0.50/sample
$34,900/system or device

Applied Biosystems
850 Linclon Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact: Andy Felton
(800) 248-0281
650 638 6045 fax
feltonac@appliedbiosystems.com

ABI 7500 Real Time PCR System

by Applied Biosystems

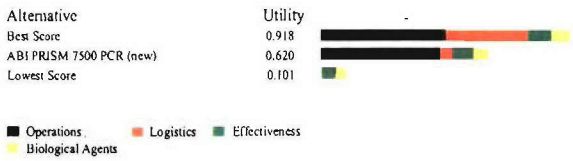
Description: The instrument is an integrated system designed to perform both real-time PCR and post-PCR analysis. The instrument is capable of analyzing 96 samples simultaneously in a 96-well plate format. The instrument provides specialized application specific software that collects and analyzes the fluorescence data for the application of absolute quantitation and allelic discrimination/SNP (Single Nucleotide Polymorphism) detection.

Technology: The instrument support two homogeneous reaction chemistries, the fluorogenic 5' nuclease assay using TaqMan® probes and the SYBR® Green I double stranded DNA binding dye chemistry. The instrument utilizes a tungsten-halogen lamp, a cooled charge coupled device (CCD) camera, and multiple emission filters, to enable multiple wavelength detection. Instrument software utilizes a multicomponenting algorithm to provide precise deconvolution of multiple dye signals, to enable the simultaneous detection of multiple fluorophores with little crosstalk.

Able to Detect the Following Organisms/Toxins:	
Bacillus anthracis (1)	VEE virus (1)
E. coli 0157:H7 (1)	Hanta virus (1)
Francisella tularensis (1)	Yellow fever virus (1)
Vibrio cholera (1)	Dengue fever virus (1)
Corynebacterium diptheria (1)	Ebola viruses (1)
Burkholdera mallei (1)	Orthopox virus (1)
Burkholderia pseudomallei (1)	MS-2 bacteriophage (1)
Yersinia pestis (1)	Botulinum toxins A,B,E (1)
Coxiella burnetti (1)	SEB (1)
Rickettsia prowazekii (1)	Ricin (1)
Brucella species (1)	
Marburg virus (1)	
Rift Valley fever virus (1)	

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

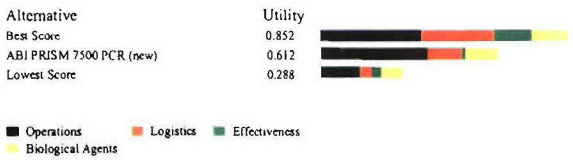
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

ABI 7500 System ranked in the middle third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.

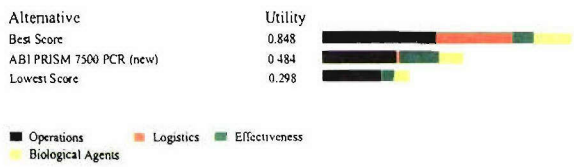
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

ABI 7500 System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

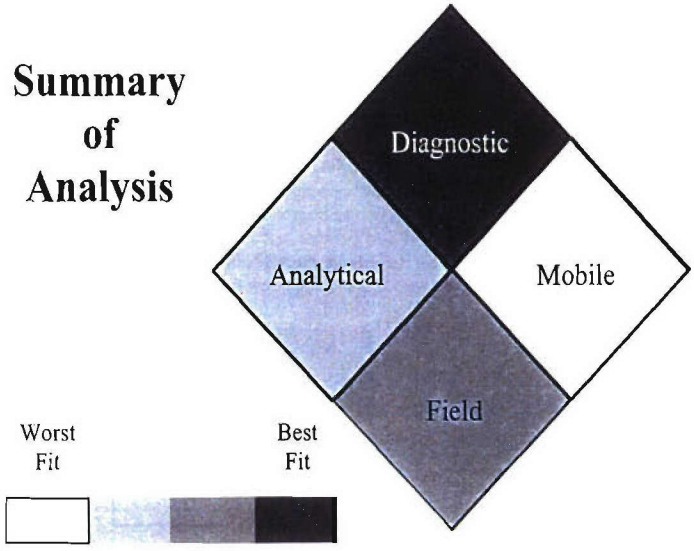
ABI 7500 System ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

ABI 7500 System ranked in the middle third of all evaluated products for field use and earned 68% of the utility points of the best score.

Summary of Analysis



ABI 7500 Real Time PCR System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

Reagents available from the Critical Reagents Program. Call 410-436-5562 for more information.

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 5 or more consumable or expendable needed
- Once a year service required
- Expected life is between 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry on luggage
- Between 25 and 50 kg
- Shelf life measure not applicable

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components must be stored at 4°C
- The performance of the device or system is not influenced by relative humidity

Cost: $0.50/sample
$42,500/system or device

Applied Biosystems
850 Linclon Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact: Andy Felton
(800) 248-0281
650 638 6045 fax
feltonac@appliedbiosystems.com

Automated Bioaerosol Collection and Detection System (ABCDS)

by Constellation Technology

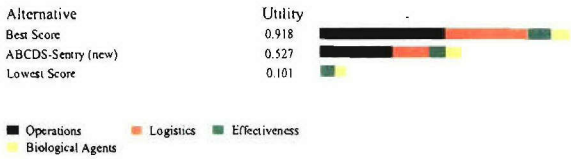
Description: The Automated Bioaerosol Collection and Detection System (**ABCDS**) is a fully automated bio-warning system. This system can detect bacteria and identify the genus and species as well as detect and identify viruses and toxins. The goal of the technology is to provide remote point detection of multiple biological agents in ambient air. The system integrates an aerosol collector, a sensor and a processor which provide the ability to collect air samples, load samples on the sensor, collect and analyze data and determine a positive signal without manual intervention. All components of the sensing element, the waveguide and reagents are reusable therefore operating costs are minimal, approximately 57 cents per assay for 4 agents in duplicate (ROM estimate, not sale price). Low operating costs, reusable tests and quick analysis make it feasible for the ABCDS to continously monitor ambient air, obviating the need for a trigger. This would allow the ABCDS to be used in the role of the traditional trigger as well as a collector/identifier. Additional cost and weight benefits would also be realized.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
MS-2 bacteriophage (1)
SEB (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The technology utilizes sandwich fluorescence immunoassays to detect and identify target analytes. The assays are performed on the surface of a planar waveguide using a patterned array of immobilized antibodies to provide a means of capturing a target analyte from the sample. Processing on the planar waveguide with a cocktail of fluorescent tracer antibodies results in the formation of fluorescent immunocomplexes, or "sandwiches." Upon evanescent excitation of the fluorescent immunocomplexes by a small diode laser, a CCD camera detects the pattern of fluorescent tracer spots on the sensor surface, and image analysis software correlates the position and intensity of the fluorescent signals with a signal that an agent has been detected and the identity of that agent. Current laboratory testing has consistently achieved test times of approximately 10 minutes in both manual and automated testing modes. In the continuous assay configuration, each of the 14 lanes of the flow cell intersects 12 separate tests on the waveguide. Each lane on the flow cell has the ability to run a complete, independent automated assay. The outer two lanes of the flow cell are used for positive controls, leaving the inner 12 lanes for assaying individual samples. The 12 lanes are used to accomplish batch analysis in continuous succession of sample fluid from an air collector. An aliquot of fluid sample from the collector is introduced into the first lane and an assay of that sample is initiated. This assay will take approximately 10 minutes to complete. During this time, subsequent aliquots are introduced into subsequent lanes and assays are initiated in each lane respectively. When the assay in the last lane is completed, the next aliquot is introduced into the first lane and the sequence is repeated. When a positive is detected in a particular lane, an alarm is indicated. It should be pointed out that reconfiguration of the automated analysis to accomodate other test situations, such as simultaneous analysis of different samples or other types of batch analyses that do not require continuous succession, is easily accommodated.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

ABCDS ranked in the bottom third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

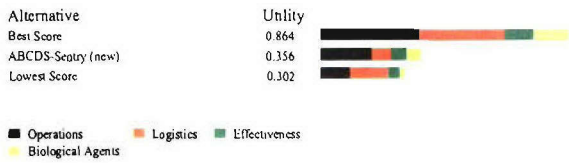
ABCDS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

ABCDS ranked in the bottom third of all evaluated products for mobile laboratories and earned 42% of the utility points of the best score.

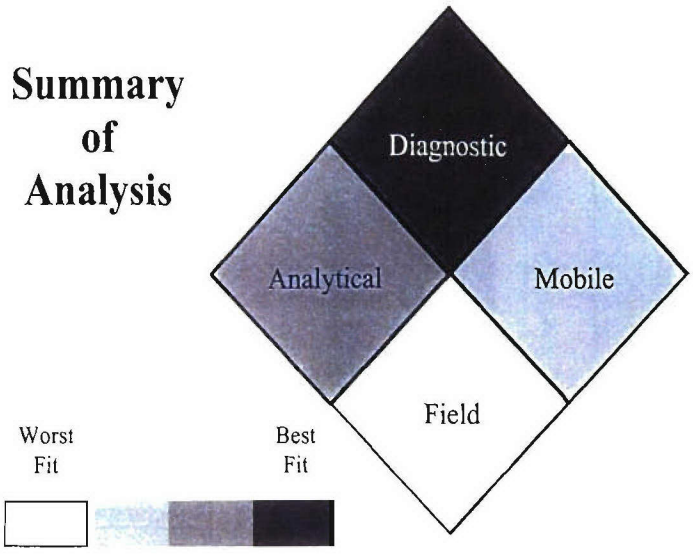
Field Use Ranking



Preference Set = Field Use

ABCDS ranked in the bottom third of all evaluated products for field use and earned 41% of the utility points of the best score.

Summary of Analysis



Automated Bioaerosol Collection and Detection System (ABCDS)

Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 1 samples/batch
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- An afternoon of training
- 10-20 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 3 solution or buffer used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumable or expendable needed
- Service needs are unknown
- Expected life measure unknown
- 10-20 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months - 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- BTUS generated unknown

Operational conditions:
- Operated from 25°C to 37°C
- Components must be stored at 4°C
- The influence on performance of the device or system by relative humidity is unknown

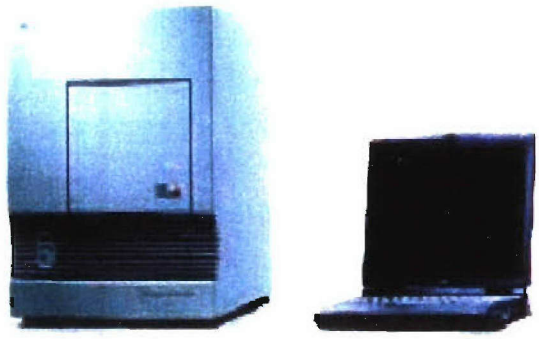
Cost: $0.21/sample
$80,000/device or system

Constellation Technology
7887 Bryan Dairy Road, Suite 100
Largo, FL 33777
www.contech.com

Point of Contact: Tammy Santana
727-547-0600 x 6400
727-545-6150 fax
santana@contech.com

ABI PRISM 7000 Sequence Detection System

by Applied Biosystems



Able to Detect the Following Organisms:
Bacillus anthracis (1)
E. coli 0157:H7 (1)
Francisella tularensis (1)
Vibrio cholera (1)
Corynebacterium diptheria (1)
Burkholdera mallei (1)
Burkholderia pseudomallei (1)
Yersinia pestis (1)
Coxiella burnetti (1)
Rickettsia prowazekii (1)
Brucella species (1)
Marburg virus (1)
Rift Valley fever virus (1)
VEE virus (1)
Hanta virus (1)
Yellow fever virus (1)
Dengue fever virus (1)
Ebola viruses (1)
Orthopox virus (1)
MS-2 bacteriophage (1)

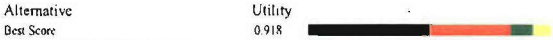
(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Description: The instrument is an integrated system designed to perform both real-time PCR and post-PCR analysis. The instrument is capable of analyzing 96 samples simultaneously in a 96-well plate format. The instrument provides specialized application specific software that collects and analyzes the fluorescence data for the application of absolute quantitation and allelic discrimination/SNP (Single Nucleotide Polymorphism) detection.

Technology: The instrument support two homogeneous reaction chemistries, the fluorogenic 5' nuclease assay using TaqMan® probes and the SYBR® Green I double stranded DNA binding dye chemistry. The instrument utilizes a tungsten-halogen lamp, a cooled charge coupled device (CCD) camera, and a four position emission filter wheel, to enable multiple wavelength detection. Instrument software utilizes a multicomponenting algorithm to provide precise deconvolution of multiple dye signals, to enable the simultaneous detection of multiple fluorophores with no crosstalk.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
ABI PRISM 7000 PCR (unchanged)	0.866
Lowest Score	0.101

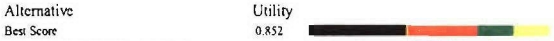


Preference Set = Analytical Laboratory

ABI PRISM 7000 Sequence Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 94% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
ABI PRISM 7000 PCR (unchanged)	0.792
Lowest Score	0.288

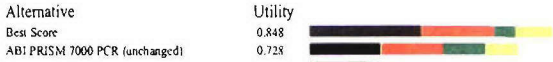


Preference Set = Diagnostic Laboratory

ABI PRISM 7000 Sequence Detection System ranked in the top third of all evaluated products for diagnostic laboratoriesand earned 93% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
ABI PRISM 7000 PCR (unchanged)	0.728
Lowest Score	0.298

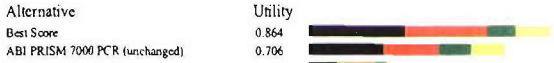


Preference Set = Mobile Laboratory

ABI PRISM 7000 Sequence Detection System ranked in the top third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.

Field Use Ranking

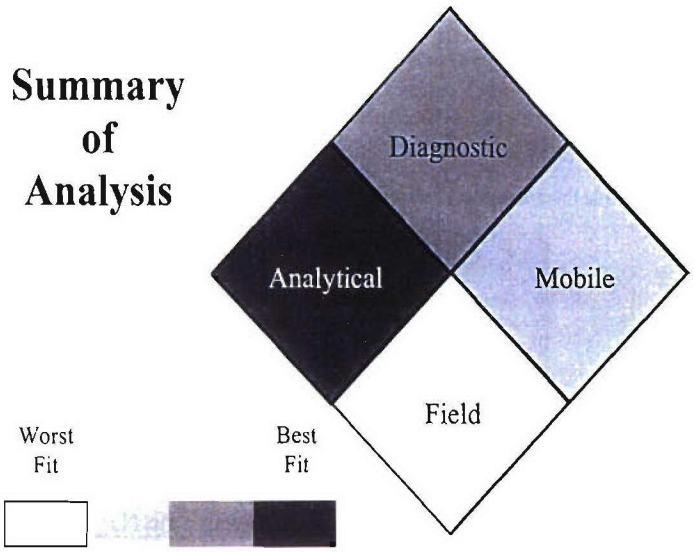
Alternative	Utility
Best Score	0.864
ABI PRISM 7000 PCR (unchanged)	0.706
Lowest Score	0.302



Preference Set = Field Use

ABI PRISM 7000 Sequence Detection System ranked in the top third of all evaluated products for field use and earned 82% of the utility points of the best score.

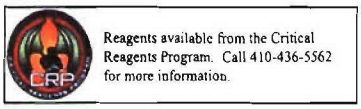
Summary of Analysis



ABI PRISM 7000 Sequence Detection System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications



System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting two or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $0.50/sample not including sample prep.
$42,761 GSA price/system or device

Applied Biosystems
850 Linclon Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact: Andy Felton
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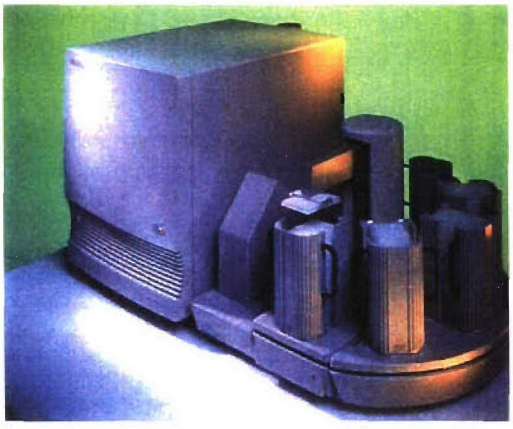
ABI PRISM 7900HT Sequence Detection System

by Applied Biosystems



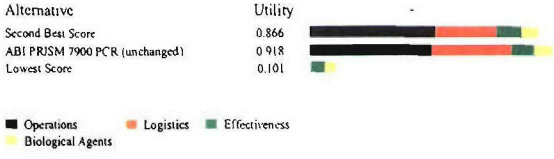
Description: The instrument is an integrated system designed to perform both real-time PCR and post-PCR analysis. The instrument is capable of analyzing 384 samples simultaneously in a 384-well plate format. The instrument provides specialized application specific software that collects and analyzes the fluorescence data for the application of absolute quantitation and allelic discrimination/SNP (Single Nucleotide Polymorphism) detection.

Able to Detect the Following Organisms/Toxins:	
Bacillus anthracis (1)	VEE virus (1)
E. coli 0157:H7 (1)	Hanta virus (1)
Francisella tularensis (1)	Yellow fever virus (1)
Vibrio cholera (1)	Dengue fever virus (1)
Corynebacterium diptheria (1)	Ebola viruses (1)
Burkholdera mallei (1)	Orthopox virus (1)
Burkholderia pseudomallei (1)	MS-2 bacteriophage (1)
Yersinia pestis (1)	Botulinum toxins A,B,E (1)
Coxiella burnetti (1)	SEB (1)
Rickettsia prowazekii (1)	Ricin (1)
Brucella species (1)	
Marburg virus (1)	
Rift Valley fever virus (1)	

Technology: The instrument can support two homogeneous reaction chemistries, the fluorogenic 5' nuclease assay using TaqMan® probes and the SYBR® Green I double stranded DNA binding dye chemistry. The instrument has an argon ion laser excitation source (488 nm), and utilize a spectrograph and charge coupled device (CCD) camera to enable continuous wavelength detection from 500-660 nm. Instrument software should utilize a multicomponenting algorithm to provide precise deconvolution of multiple dye signals to enable the simultaneous detection of multiple fluorophores. The instrument can process at least 5,000 real-time quantitative PCR sample wells per day (24 hour period), and at least 30,000 SNP genotyping samples every 2.5 hours.

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

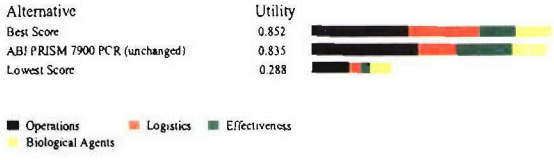
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

ABI PRISM 7900 Sequence Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 100% of the utility points of the best score.

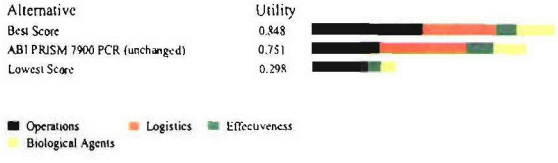
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

ABI PRISM 7900 Sequence Detection System ranked in the top third of all evaluated products for diagnostic laboratories and earned 98% of the utility points of the best score.

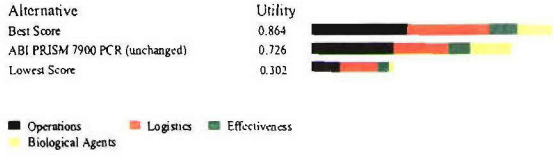
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

ABI PRISM 7900 Sequence Detection System ranked in the top third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

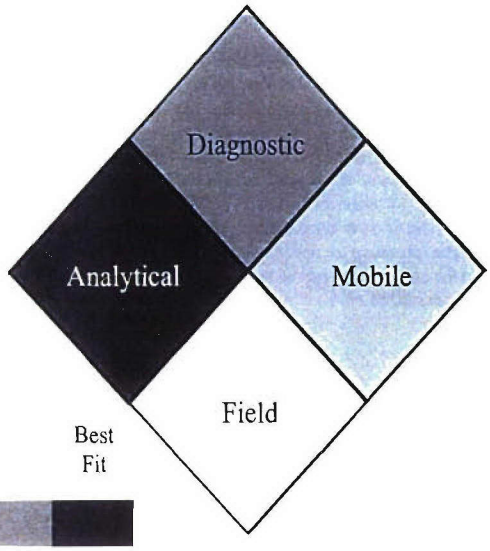
Field Use Ranking



Preference Set = Field Use

ABI PRISM 7900 Sequence Detection System ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

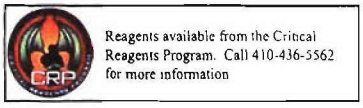
Summary of Analysis



ABI PRISM 7900HT Sequence Detection System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications



System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Less than once a year service required
- Expected life greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- Between 5 and 25 kg
- Shelf life greater than 3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

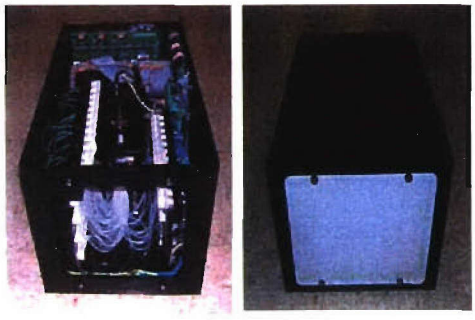
Cost: $0.50/sample
$90,000 GSA price/system or device

Applied Biosystems
850 Linclon Center Drive
Foster City, CA 94494
www.Appliedbiosystems.com

Point of Contact: Andy Felton
(800) 248-0281
650 638 6045 fax
feltonac@appliedbiosystems.com

Automated Continuous Analysis Array Biosensor (ACA-ABS)

by Constellation Technology



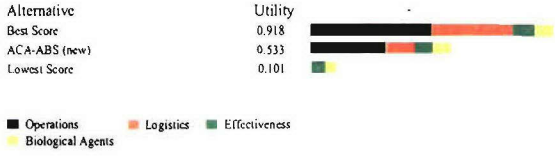
Description: The Automated, Continuous Analysis – Array Bio-Sensor (ACA-ABS) is a fully automated bio-warning system. This system can detect bacteria and identify the genus and species as well as detect and identify viruses and toxins. The goal of the technology is the simultaneous automatic analysis of up to 12 samples or a continuous sampling stream for multiple biological agents in about 10 minutes. All components of the sensing element, the waveguide and reagents are reusable therefore operating costs are minimal; approximately 57 cents per assay for 4 agents in duplicate (ROM estimate, not sale price). Low operating costs, reusable tests and quick analysis make it feasible for the ACA-ABS to continuously monitor a sample stream, obviating the need for a trigger. This would allow the ACA-ABS to be used in the role of the traditional trigger as well as an identifier. Additional cost and weight benefits would also be realized.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
MS-2 bacteriophage (1)
SEB (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The technology utilizes sandwich fluorescence immunoassays to detect and identify target analytes. The assays are performed on the surface of a planar waveguide using a patterned array of immobilized antibodies to provide a means of capturing a target analyte from the sample. Processing on the planar waveguide with a cocktail of fluorescent tracer antibodies results in the formation of fluorescent immunocomplexes, or "sandwiches." Upon evanescent excitation of the fluorescent immunocomplexes by a small diode laser, a CCD camera detects the pattern of fluorescent tracer spots on the sensor surface, and image analysis software correlates the position and intensity of the fluorescent signals with a signal that an agent has been detected and the identity of that agent. Current laboratory testing has consistently achieved test times of approximately 10 minutes in both manual and automated testing modes. In the continuous assay configuration, each of the 14 lanes of the flow cell intersects 12 separate tests on the waveguide. Each lane on the flow cell has the ability to run a complete, independent automated assay. The outer two lanes of the flow cell are used for positive controls, leaving the inner 12 lanes for assaying individual samples. The 12 lanes are used to accomplish batch analysis in continuous succession of sample fluid from an air collector. An aliquot of fluid sample from the collector is introduced into the first lane and an assay of that sample is initiated. This assay will take approximately 10 minutes to complete. During this time, subsequent aliquots are introduced into subsequent lanes and assays are initiated in each lane respectively. When the assay in the last lane is completed, the next aliquot is introduced into the first lane and the sequence is repeated. When a positive is detected in a particular lane, an alarm is indicated. It should be pointed out that reconfiguration of the automated analysis to accommodate other test situations, such as simultaneous analysis of different samples or other types of batch analyses that do not require continuous succession, is easily accommodated.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

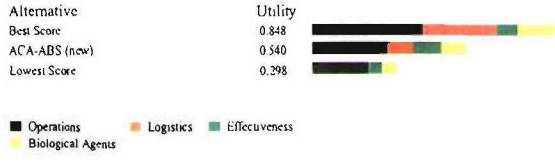
ACA-ABS ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

ACA-ABS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.

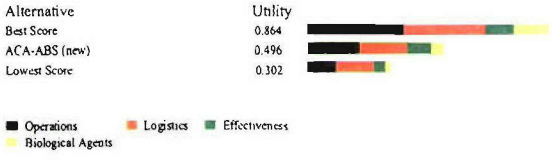
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

ACA-ABS ranked in the middle third of all evaluated products for mobile laboratories and earned 64% of the utility points of the best score.

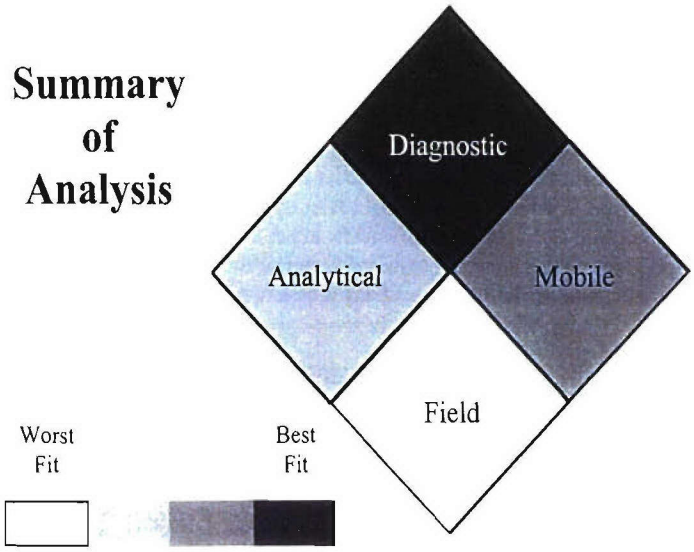
Field Use Ranking



Preference Set = Field Use

ACA-ABS ranked in the bottom third of all evaluated products for field use and earned 57% of the utility points of the best score.

Summary of Analysis



Automated Continuous Analysis Array Biosensor (ACA-ABS)

Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief training
- 10-20 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 2 solution or buffer used
- 5 or more components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Service needs are unknown
- Expected life measure unknown
- 10-20 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- Between 25-50 kg
- Shelf life between 6 months - 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- One additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- BTUS generated unknown

Operational conditions:
- Operated from 25°C to 37°C
- Components must be stored at 4°C
- The influence on performance of the device or system by relative humidity is unknown

Cost: $0.21/sample
$40,000/device or system

Constellation Technology
7887 Bryan Dairy Road, Suite 100
Largo, FL 33777
www.contech.com

Point of Contact: Tammy Santana
727-547-0600 x 6400
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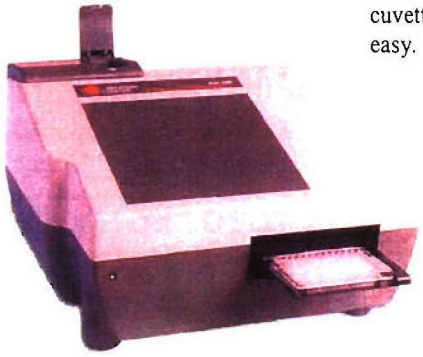
santana@contech.com

AD 200 Absorbance Detector

by Beckman Coulter

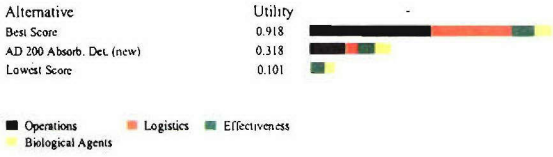
Description: The AD 200 Absorbance Detector is intended to be used for research applications including colorimetric immunoassays, such as ELISAs, reporter assays, and protein quantification assays. The AD 200 is capable of measuring assays in 6-384 well plates and cuvettes. The AD 200 can perform measurements in multiple modes including single wavelength, dual wavelength, kinetic, linear scan, area scan and spectral scan. Full programming and data analysis are available either through powerful on-board software or via the use of a remote PC and software. Preprogrammed cuvette applications make nucleic acid and protein quantitation quick and easy.



No Formal Detection Assays Available

Technology: The AD 200 Absorbance Detector employs a controlled tungsten halogen lamp and a deuterium lamp as light sources and a single silicon photodiode as the detector for measuring light (absorbance) in the 190 – 1000nm wavelength range. It employs the use a grating monochromator to select specific wavelengths to measure, and has a dynamic range to 4.0 OD. In addition, the AD 200 features programmable shaking and temperature control options for microplate measurements.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

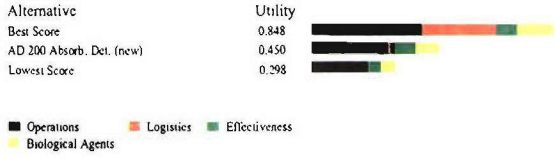
AD 200 ranked in the bottom third of all evaluated products for analytical laboratories and earned 35% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

AD 200 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

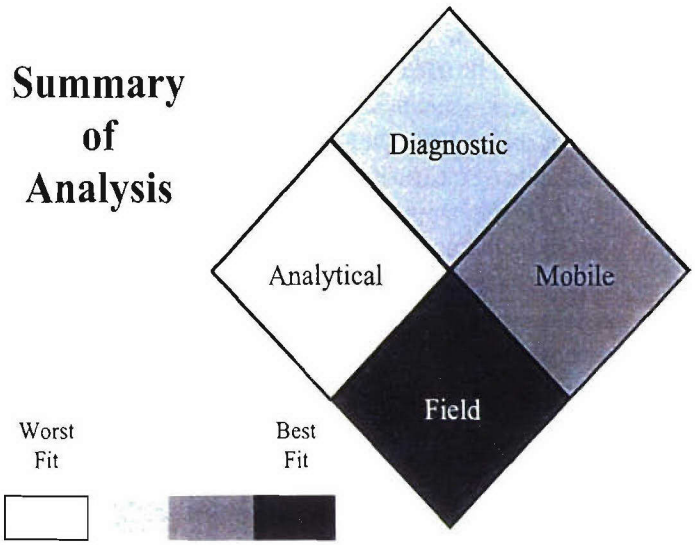
AD 200 ranked in the bottom third of all evaluated products for mobile laboratories and earned 53% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

AD 200 ranked in the bottom third of all evaluated products for field use and earned 60% of the utility points of the best score.

Summary of Analysis



AD 200 Absorbance Detector

Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- Number of solutions or buffers used is assay dependent
- 1 component
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Needs service once a year
- Expected system or device life of 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry on luggage suitcase
- Between 5 and 25 kg
- Shelf life measure is not applicable

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System is able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting 4 or more targets in a single well
- 2 additional pieces of equipment needed

Signature:
- No sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components storage conditions are not applicable
- Device or system has peak performance at normal relative humidity conditions only

Cost: $unknown/sample
$15,950.00-$18,950.00/device

Beckman Coulter
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact:
Matt Maloney, Margaret Kelly
(317) 808-4217, (714) 773-8022
fax.(714) 773-6690
MJMaloney@beckman.com
mmkelly@beckman.com

AD 340 Absorbance Detector

by Beckman Coulter, Inc.

Description: The AD 340 Absorbance Detector is intended to be used for research applications including colorimetric immunoassays, such as ELISAs, reporter assays, and protein quantification assays. The AD 340 is capable of measuring assays in 6-384 well plates. The AD 340 can perform measurements in multiple modes including single wavelength, dual wavelength, kinetic, linear scan and area scan. Full programming and data analysis are available either through powerful on-board software or via the use of a remote PC and software.

Able to Detect any Organisms/Toxins with a Colormetric Assay with Appropriate Wavelength Range:

Technology: The AD 340 Absorbance Detector employs a controlled tungsten halogen lamp as a light source and a single silicon photodiode as the detector for measuring light (absorbance) in the 340 – 750nm wavelength range. It employs the use of filters to select specific wavelengths to measure, and has a dynamic range to 4.0 OD. In addition, the AD 340 features programmable shaking and temperature control options.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
AD 340 Absorb. Det (update)	0.336
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

AD 340 Absorbance Detector ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
AD 340 Absorb. Det. (update)	0.463
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

AD 340 Absorbance Detector ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
AD 340 Absorb. Det. (update)	0.474
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

AD 340 Absorbance Detector ranked in the bottom third of all evaluated products for mobile laboratories and earned 56% of the utility points of the best score.

Field Use Ranking

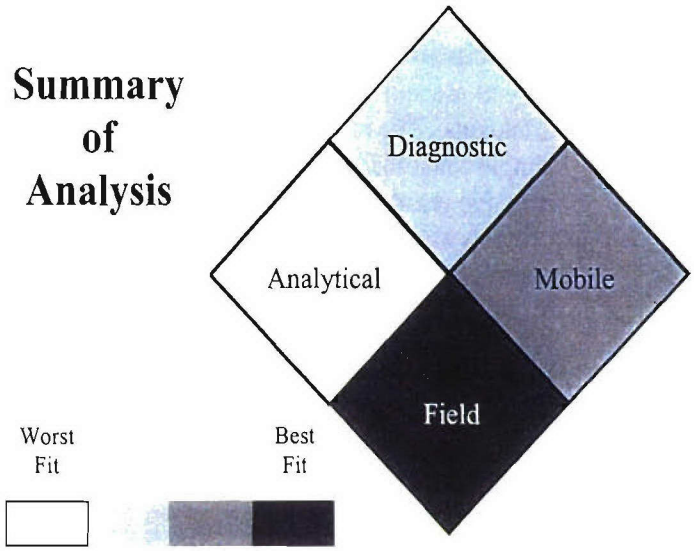
Alternative	Utility
Best Score	0.864
AD 340 Absorb. Det. (update)	0.581
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

AD 340 Absorbance Detector ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

Summary of Analysis



AD 340 Absorbance Detector Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- NA solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- NA shelf life

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- NA storage of components
- Device or system has peak performance at normal relative humidity conditions only

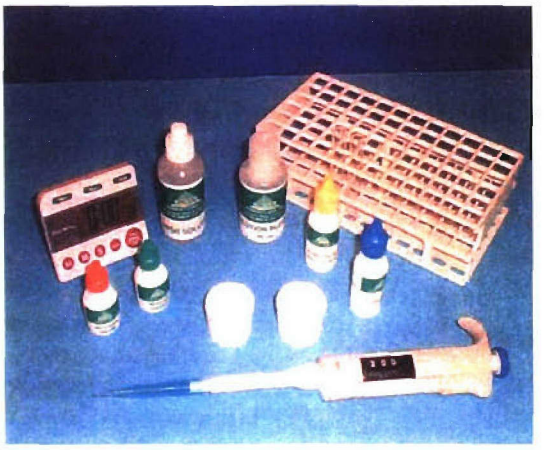
Cost: $ unknown/sample
$7,995.00-8,995.00/system or device

Beckman Coulter, Inc.
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact: Matt Maloney or Margaret Kelly
(317) 808-4217, (714) 773-8022
(714) 773-6690 fax
MJMaloney@beckman.com
mmkelly@beckman.com

AflaCup Test Kit

by International Diagnostic Systems



Description: The AflaCup provides a fast, easy to use and reliable means to test for total aflatoxins. The result is easily interpreted by a simple color change: a blue dot denotes a negative result, a white cup means the sample contains aflatoxin above the detection limit. To comply with various accuracy needs, test kits are available for a 10 to 20 ppb detection limit. Dilution schemes allow for further detection limits.

Able to Detect the Following Toxin:
Aflatoxins

Technology: The AflaCup is a qualitative test based on solid phase immunoassay technology in which an antibody binds specifically with aflatoxin. This rapid qualitative screen has been specifically developed for grain elevator operators, cottenseed dealers, tree nut handlers and pet food companies.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
AflaCup Test Kit ELISA (unchanged)	0.163
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

AflaCup Test Kit ranked in the bottom third of all evaluated products for analytical laboratories and earned 18% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
AflaCup Test Kit ELISA (unchanged)	0.374
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

AflaCup Test Kit ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 44% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
AflaCup Test Kit ELISA (unchanged)	0.453
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

AflaCup Test Kit ranked in the bottom third of all evaluated products for mobile laboratories and earned 53% of the utility points of the best score.

Field Use Ranking

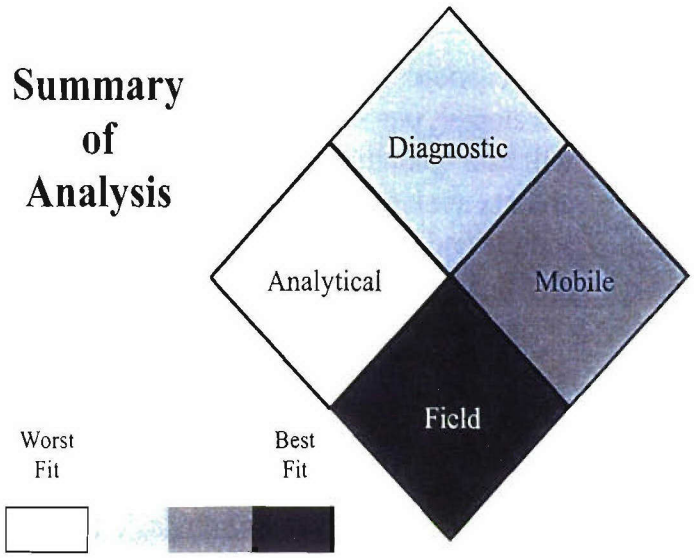
Alternative	Utility
Best Score	0.864
AflaCup Test Kit ELISA	0.547
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

AflaCup Test Kit ranked in the middle third of all evaluated products for field use and earned 63% of the utility points of the best score.

Summary of Analysis



AflaCup Test Kit Evaluation Criteria Provided by Vendor

Sensitivity:
- NA CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is not amendable to automation

Training/Speed/Manpower:
- Very brief training
- 10-20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 4 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- There is a single shaking or vortexing step
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: Approx. $5.00-7.00/sample
$130.00-185.00/system or device

Romer Labs, Inc.
1301 Stylemaster Drive
Union, MO 63084-1156
www.romerlabs.com

Point of Contact: Sales Department
(636) 583-8600
fax. (636) 583-6553
sales@romerlabs.com

Anthragen

by Collaborative Genetics

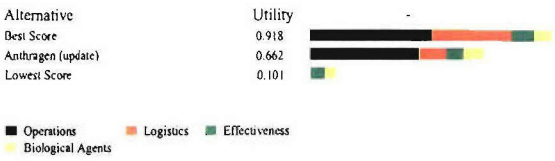
Description: We are currently developing our first product. The product will be a qualitative device that can detect anthrax spores in an environmental sample and the LF and PA in whole blood within 5 minutes.

Able to Detect the Following Organism/Toxin:
Bacillus anthracis (1)
Botulinum toxin A (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The device will be an antibody/antigen-based product that is a sandwich assay. The device will contain a filter that is treated with biologics that will lyse the blood cells to extract the toxins and will capture red blood cells and allow only plasma further down the lateral flow device.

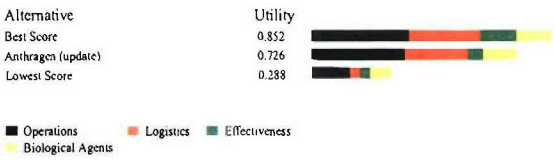
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Anthragen ranked in the middle third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.

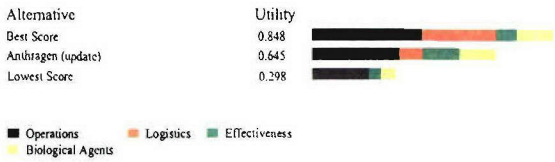
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Anthragen ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

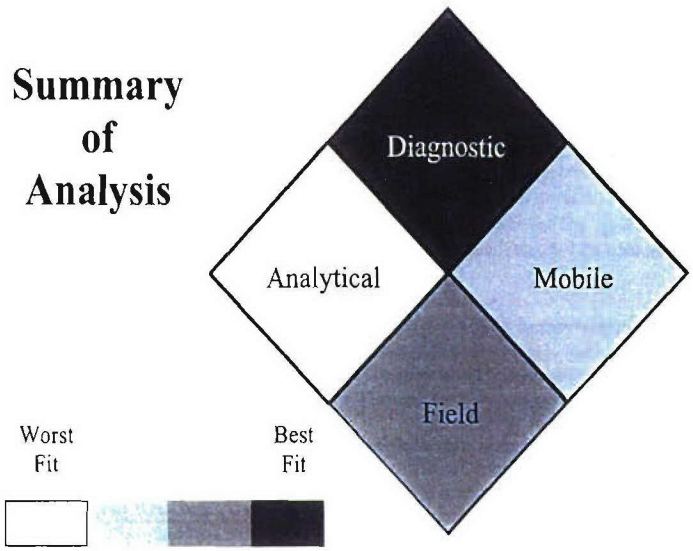
Anthragen ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

Anthragen ranked in the top third of all evaluated products for field use and earned 82% of the utility points of the best score.

Summary of Analysis



Anthragen Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- Only one incomplete device or system exist (bread board)

System requirements:
- The system or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 50 µl volume needed per test for detection
- The system or approach could easily be adapted to a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 min set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for multiple detection assays
- 0-1 solution or buffer used
- 3 components
- Cleaning with 70% isopropanol required

Maintenance:
- 0-1 consumable or expendable needed
- Needs service less than once a year
- Expected life measure is greater than 10 years
- Less than 5 min required for daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 to 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System is able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: Approximately $3.00/sample
$40.00/system or device

Collaborative Genetics
1152 Bond Ave
Rexburg, ID 83440
www.collaborativegenetics.com

Point of Contact: Bruce J. Tedeschi
(208) 359-2446
btedeschi@collaborativegenetics.com

Autonomous Pathogen Detection System (APDS)

by Lawrence Livermore National Lab (LLNL)

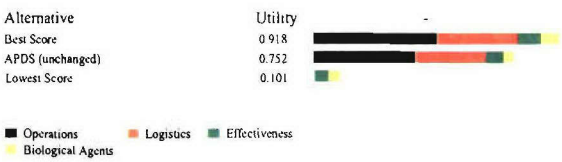
Description: A stand-alone system for rapid, continuous monitoring of multiple airborne biological threat agents in the environment has been developed. This system, the autonomous pathogen detection system (APDS), acts as a "biosmoke alarm" and is targeted for protection of domestic applications such as the Olympics, mass transit systems, and other high profile targets in which the public is at high risk to bioterrorist attacks. The APDS is completely automated, offering aerosol sampling, in-line sample preparation fluidics, and orthogonal immunoassay and nucleic acid detection device. This system has flexibility, cost, and system performance and should be compared to competing technologies.

Technology: The objective of this research project is to develop a stand-alone pathogen detection system capable of rapid, continuous, low cost environmental monitoring of multiple airborne biological threat agents. The final APDS will be completely automated, offering aerosol sampling, in-line sample preparation fluidics, multiplex detection and identification immunoassays, and orthogonal, multiplexed PCR (nucleic acid) amplification and detection. While the primary focus has been on protection of civilians from terrorist attacks, the same system could also have a role in protecting military personnel from biological warfare attacks. APDS instruments can be used at high profile events such as the Olympics for short-term, intensive monitoring or more permanent installation in major public buildings or transportation nodes. All of these units can be networked to a single command center so that a small group of technical experts could maintain and respond to alarms at any of the sensors. The APDS has several key advantages over competing technologies: (1) the ability to measure up to 100 different agents and controls in a single sample, (2) the flexibility and ease with which new bead-based assays can be developed and integrated into the system, (3) the presence of an orthogonal, real-time detection module for highly sensitive and selective nucleic acid amplification and detection, (4) the ability to use the same basic system components for multiple deployment architectures, and (5) the relatively low cost per assay (<$1 per 10-plex or $0.10 per assay) and minimal consumables. The object of this 2-year proposal is to complete development and testing of the APDS-II (multiplexed immunoassay screen followed by nucleic acid confirmation) and APDS-III (multiplexed immunoassays and multiplexed nucleic acid detection) platforms.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
Francisella tularensis (1)
Yersinia pestis (1)
Vibrio cholera (1)
Coxiella burnetti (1)
Marburg virus (1)
VEE virus (1)
Orthopox virus (1)
MS-2 bacteriophage (1)
Botulinum toxins A,B,E (1)
SEB (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

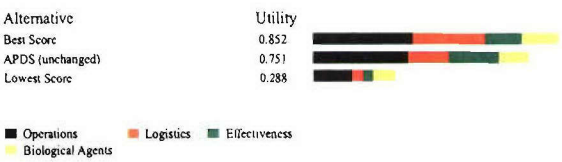
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

APDS ranked in the top third of all evaluated products for analytical laboratories and earned 82% of the utility points of the best score.

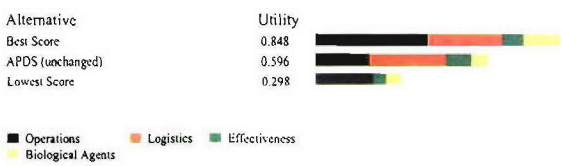
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

APDS ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

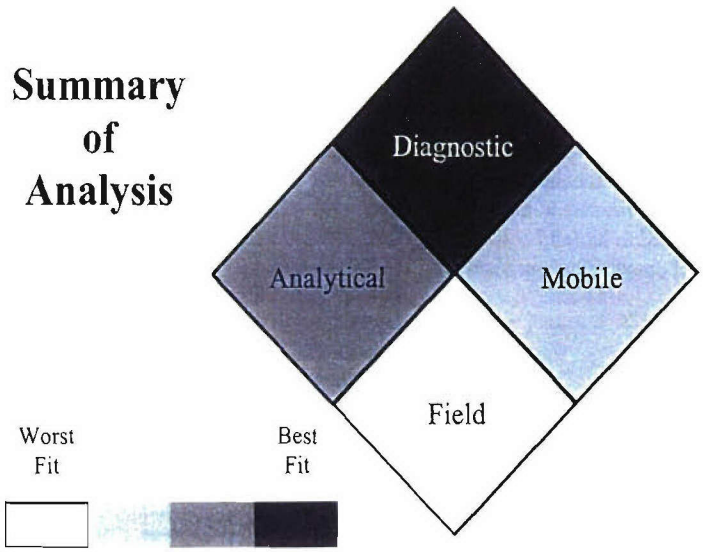
APDS ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

APDS ranked in the bottom third of all evaluated products for field use and earned 51% of the utility points of the best score.

Summary of Analysis



Autonomous Pathogen Detection System (APDS) Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 1 sample/batch
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- An afternoon of training
- Greater than 20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 3 consumable or expendable needed
- More often than every 6 months service required
- NA expected life
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Larger than a home dishwasher
- Between 25 and 50 kg
- Shelf life less than 1 month

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Unknown performance of the device or system in relative humidity

Cost: $0.10/sample
$150,000.00/system or device

Lawrence Livermore National Lab
7000 East Ave, L-174
Livermore, CA 94550

Point of Contact: Bill Colston
(925) 423-0375
fax. (925) 424-2778
colston@llnl.gov

APSIS (Assay Processing and Specific Identification System)

by Bruker Daltonik GmbH

Description: Bruker Daltonics -20 years of tradition, flexibility and performance in chemical, biological and nuclear detection. The newly developed APSIS is an identifier for harmful pathogens, like bacteria, spores and viruses, based on their genomic fingerprint stored in their DNA or RNA. The system is intended for the on site analysis of microorganisms (bacteria, spores and viruses) in mobil labs and onboard vehicles. The performance is not limited to harmful pathogens used as BWA but covers also pathogens for clinical diagnostical purposes.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli O157:H7 (1)
Orthopox virus (1)
Smallpox virus (1)
MS-2 bacteriophage (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: APSIS cartridge combines two current technologies for detection: In the first step the target DNA/RNA is amplified by PCR to achieve a detectable amount of DNA/RNA. The second step is the hybridisation against sample sequences on the glass substrate within the presence of the same buffer and the same volume where PCR was performed. The fluorescence pattern is readout by fluorescence detection giving a characteristic pattern. The pattern is evaluated by a dedicated software tool. The design of the processing cartridge is optimised for minimal user interaction. An integrated EPROM gives a complete process control and enables the cartridge to be completely self describing for protocol purposes. The APSIS System has a modular design consisting of a process station with eight parallel but independently operating processing slots for thermal and fluid processing and a reader unit. Inside the reader unit the fluorescence readout is performed using microscope optics.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
APSIS (new)	0.703
Lowest Score	0.101

Preference Set – Analytical Laboratory

APSIS ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
APSIS (new)	0.677
Lowest Score	0.288

Preference Set – Diagnostic Laboratory

APSIS ranked in the middle third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
APSIS (new)	0.550
Lowest Score	0.298

Preference Set – Mobile Laboratory

APSIS ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.

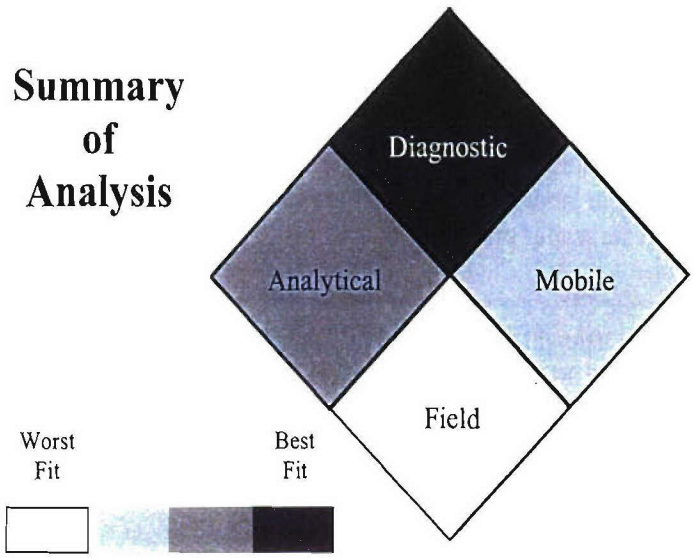
Field Use Ranking

Alternative	Utility
Best Score	0.864
APSIS (new)	0.542
Lowest Score	0.302

Preference Set – Field Use

APSIS ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.

Summary of Analysis



APSIS Identification System

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device has 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 50-60 min
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 3 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumable or expendable needed
- Needs service once a year
- Expected life measure of 5-10 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at 25°C to 37°C
- Performance of the device or system is not influenced by relative humidity

Cost: $50/sample
$115,000/device or system

Bruker Daltonik GmbH
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Leipzig, D-04318 Germany
www.bdal.de

Point of Contact: Dr. Norbert Klöpper
+493412431448
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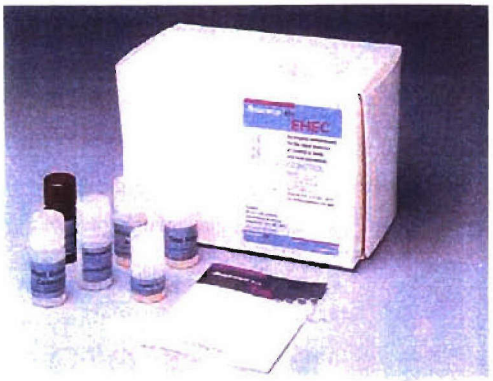
nkl@bdal.de

Assurance EHEC EIA

by BioControl Systems, Inc.



Description: Assurance EIAs are enzyme immunoassays (EIAs) for food and environmental testing. These tests have been extensively validated through the AOAC Official Method process. Assurance EIAs are used in industry, independent and government laboratories. Results are read as a standard microplate reader printout.

Assurance EIAs are available for the detection of *Salmonella* (AOAC Official Method 992.11), *Listeria* (AOAC Official Method 996.14), and *E. coli* O157:H7 (AOAC Official Method 996.10). Also available is the Assurance Gold EIA format, a visually or instrumentally read EIA, for *Salmonella* (AOAC Official Method 999.08), and *Campylobacter*.

Able to Detect the Following Organism:
E. coli 0157:H7 (2)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Proprietary antibodies with high specificity to EHEC antigens are bound to microwell plates. Appropriately enriched test samples and positive controls are added to plates. Any EHEC antigens present will bind to microwells, forming antibody-antigen complex. Nonreactive material is washed away. Alkaline phosphatase antibody conjugate is added and, after incubation, unbound conjugate is washed away. The substrate *p*-nitrophenylphosphate, is added and absorbance of resulting colored product is read spectrophotometrically at 405-410 nm.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Assurance EHEC EIA (update)	0.578
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

Assurance EHEC EIA ranked in the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Assurance EHEC EIA (update)	0.626
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

Assurance EHEC EIA ranked in the middle third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Assurance EHEC EIA (update)	0.592
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

Assurance EHEC EIA ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.

Field Use Ranking

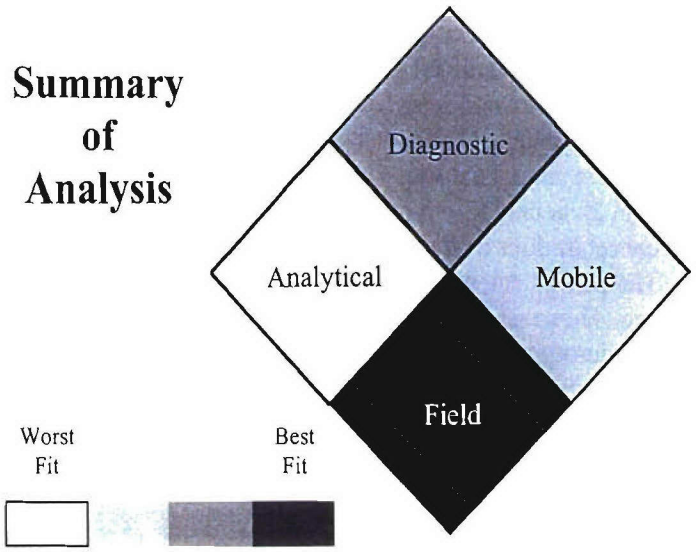
Alternative	Utility
Best Score	0.864
Assurance EHEC EIA	0.647
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

Assurance EHEC EIA ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.

Summary of Analysis



Assurance EHEC EIA Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- A single shaking or vortexing step
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

System requirements:
- System has a 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 5-10 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for multiple detection
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- NA expected life
- 5-10 minutes daily assurance procedures required

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

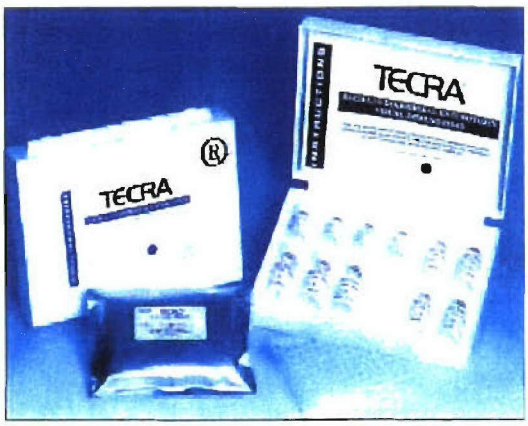
Cost: $4.00-7.00/sample
$2.50-4.00/system or device

BioControl Systems, Inc.
12822 SE 32nd St.
Bellevue, WA 98055
www.biocontrolsys.com

Point of Contact: Maritta Ko
(425) 603-1123 ext. 105
fax. (425) 603-0070
mko@biocontrolsys.com

Bacillus Diarrhoeal Enterotoxin Visual Immunoassay (VIA)

by TECRA International Pty Ltd



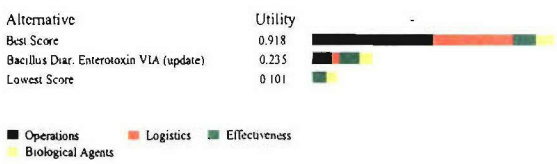
Description: A rapid and simple screening test for detection of Bacillus Diarrhoeal Enterotoxin (BDE) in food, food related samples and enrichment cultures. It can be used to detect the presence of enteroxigenic *Bacillus spp.* capable of causing diarrhoeal food poisoning, in less than 20 hours, or to directly detect the presence of BDE at concentrations as low as 1 ng per mL in 4 hours.
The ELISA can be used manually and the results read by eye. However, it can also be semi-automated with the use of microtitre plate readers and washers or fully automated for large scale testing. The kit is available in a 48 well format.

Able to Detect the Following Toxin:
Bacillus Diarrhoeal Enterotoxin (2)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The TECRA BDE VIA is an Enzyme-linked Immunoassay (ELISA) performed in a sandwich configuration.

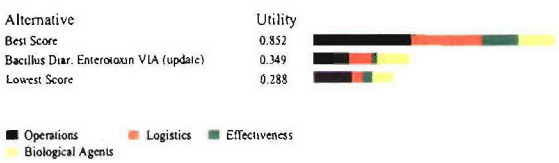
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Bacillus Diarrhoeal Enterotoxin Visual Immunoassay ranked in the bottom third of all evaluated products for analytical laboratories and earned 26% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

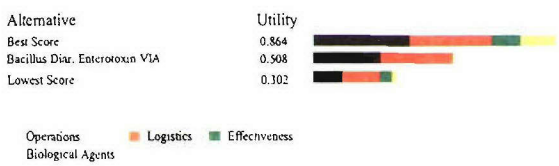
Bacillus Diarrhoeal Enterotoxin Visual Immunoassay ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 41% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

Bacillus Diarrhoeal Enterotoxin Visual Immunoassay ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.

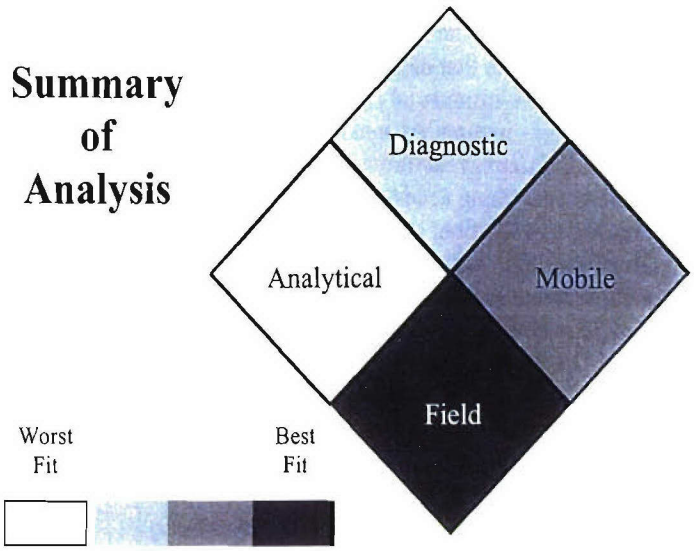
Field Use Ranking



Preference Set = Field Use

Bacillus Diarrhoeal Enterotoxin Visual Immunoassay ranked in the bottom third of all evaluated products for field use and earned 59% of the utility points of the best score.

Summary of Analysis



Bacillus Diarrhoeal Enterotoxin Visual Immunoassay (VIA) Evaluation Criteria Provided by Vendor

Sensitivity:
- NA CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- No electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 5-10 minutes required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for a single use
- More than 4 solutions or buffers used
- 5 or more components
- NA cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life measure NA
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation step
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

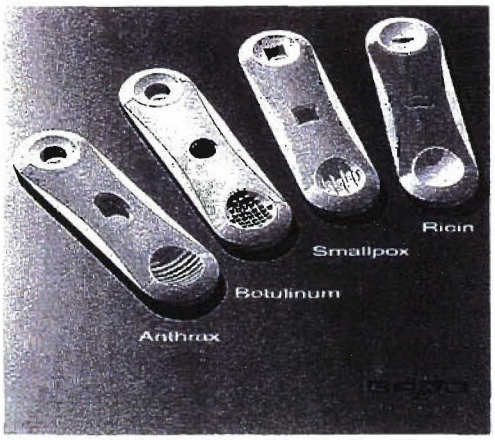
Cost: $7.00/sample
$306.00/system or device

TECRA International Pty Ltd
13 Rodborough Rd.
Frenchs Forest, NSW 2086 Australia
www.tecra.net

Point of Contact: Nick Vale
+61 2 8977011
fax. +61 2 9453 3422
nick.vale@tecra.net

BADD

by Sigma-Aldrich Fine Chemicals



Description: The BADD Anthrax Rapid Detection Device is a test available that detects minute, yet high amounts of Anthrax on environmental surfaces or in solutions. The BADD Device works without the need for extensive sample preparation steps or additional expensive equipment. Each kit contains everything necessary to take a sample and perform an immediate evaluation, anywhere in the world, with results in 15 minutes or less. Accuracy, ease of use, a capacity to detect credible threat levels, and no cross reactivity with *Bacillus globigii* or *Bacillus thuringiensis* makes the BADD Anthrax Rapid Detection Device the perfect test for field detection. In addition to anthrax detection, BADD devices are also available for ricin toxin and botulinum toxin. A test for First Responders evaluating threat credibility.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (3)
Botulinum toxins A,B,E (3)
Ricin (3)
Smallpox (3)
SEB (3)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Antigen and antibody rapid screening based on lateral flow technology.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
BADD Tickets (update)	0.533
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set – Analytical Laboratory

BADD ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
BADD Tickets (update)	0.616
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

BADD ranked in the middle third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
BADD Tickets (update)	0.742
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

BADD ranked in the top third of all evaluated products for mobile laboratories and earned 88% of the utility points of the best score.

Field Use Ranking

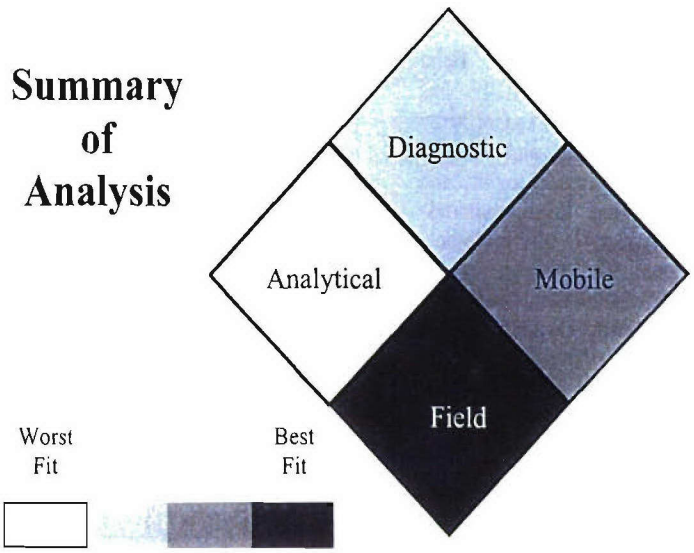
Alternative	Utility
Best Score	0.864
BADD Tickets	0.765
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

BADD ranked in the top third of all evaluated products for field use and earned 89 % of the utility points of the best score.

Summary of Analysis



BADD Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- No electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 1 samples/batch
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- There is a single shaking or vortexing step
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

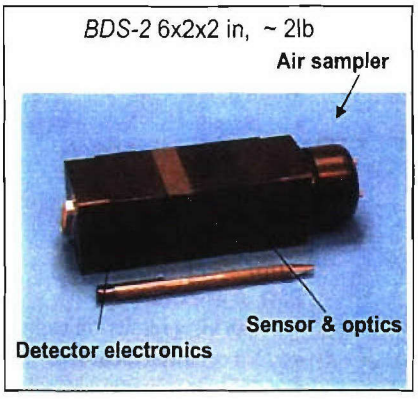
Cost: $50.00/sample
$50.00/system or device

Sigma-Aldrich Fine Chemicals
3050 Spruce Street
Saint Louis, MO 63103
www.SigmaAldrich.com

Point of Contact: Dean Lyon
(314) 286-7786 Ext. 7156
fax. (314) 652-0000
dlyon@sial.com

Biological Detection System – Generation 2 (BDS2)

by Echo Technologies, Inc.



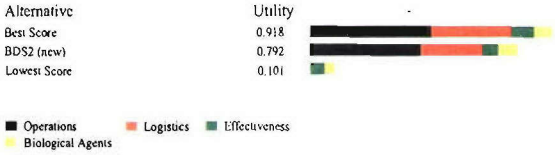
Description: Echo Technologies, Inc. (ETI) has developed an optical sensor array designed to detect and classify biological agents and toxins, and to discriminate these materials from typical non-biological interferents. The sensor array will detect BW threat agents including bacteria, bacterial spores, toxins and viruses. The system was designed to be used in two primary configurations: as a handheld, or stand-alone point detector; or as a "smart trigger" when intergrated with a larger instrumentation suite.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli O157:H7 (1)
Francisella tularensis (1)
Vibrio cholera (1)
Corynebacterium diptheria (1)
Burkholderia mallei (1)
Burkholderia pseudomallei (1)
Yersinia pestis (1)
MS-2 bacteriophage (1)
Botulinum toxin A (1)
SEB (1)
Saxitoxin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The sensors are optical transducers that use optical substrates and fluorescent reporter molecules to detect broad classes of microorganisms. Using a multi-sensor array the nature of the threat can be assessed and distinguished from non-biological material, and from the naturally occurring biological background (e.g., airborne dead bacteria, fungi, molds and humic matter). Detection of broad classes of chemical and biological threats is particularly well suited to situations where the nature of the contaminants is unknown. The information from multiple sensors in an array is analyzed as an ensemble using chemometric algorithms, thereby providing more information than an individual sensor for a single analyte. This presumptive determination can then be used to trigger an array of identification sensors or signal the need for a more sophisticated confirmatory analysis.

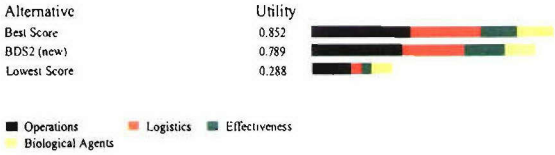
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

BDS2 ranked in the top third of all evaluated products for analytical laboratories and earned 86% of the utility points of the best score.

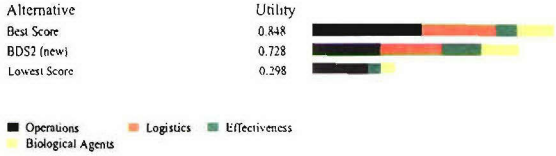
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

BDS2 ranked in the top third of all evaluated products for diagnostic laboratories and earned 93% of the utility points of the best score.

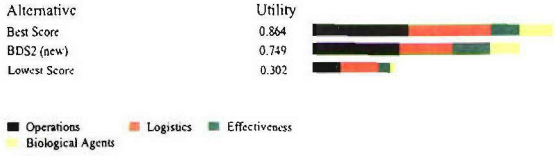
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

BDS2 ranked in the top third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.

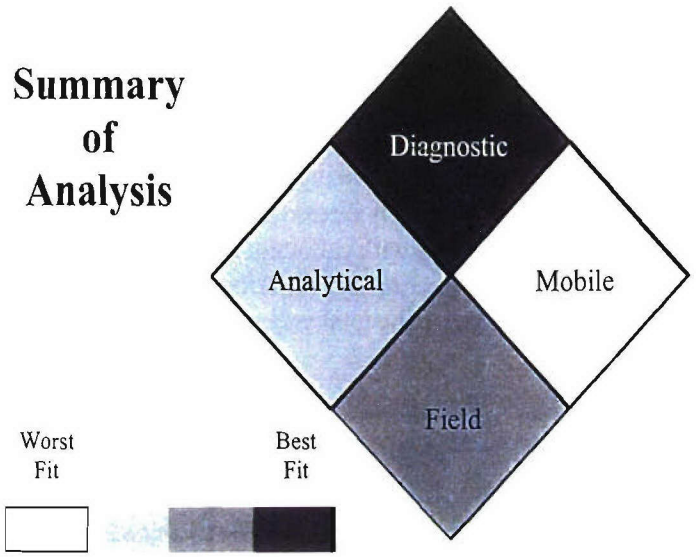
Field Use Ranking



Preference Set = Field Use

BDS2 ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

Summary of Analysis



Biological Detection System (BDS2)

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device uses batteries
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training required
- 5-10 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Needs service less than once a year
- Expected life measure of 3-5 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1-6 months

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Can be operated from 4°C to 45°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $5/sample
$10,000/device or system

Echo Technologies, Inc.
5250 Cherokee Avenue
Alexandria, VA 22312
www.echotech.net

Point of Contact: Marilyn Ripin//Mary Beth Tabacco
703-658-7692// 617-443-0066
703-941-8172// 617-204-3080 fax
mripin@erols.com//mtabacco@erols.com

Beacon Aflatoxin Plate Kit

by Beacon Analytical Systems, Inc.

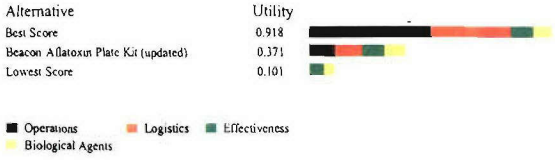
Description: The Beacon Aflatoxin Plate Kit is a competitive immunoassay for the quantification of Aflatoxin residues in grains and grain-based products. The limit of detection is 2 parts per billion. A ground sample is extracted by shaking with a 70% methanol solution. This extract is filtered and then analyzed in the immunoassay along with calibrator solutions of known Aflatoxin concentration and the Aflatoxin content of the sample is derived. The total assay time is less than 20 minutes.

Able to Detect the Following Toxins
Aflatoxin (1)
T-2 Mycotoxin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The Beacon Aflatoxin Plate Kit is based on the well-established technique of enzyme-labeled competitive immunoassays. This technique has been utilized in clinical laboratories for well over 20 years. The antibodies utilized will detect Aflatoxin B1, B2, G1 and G2 but have minimal reactivity with M1. The kit requires minimal operator training and dedicated equipment and is capable of yielding quantitative results in the range of 2 to 50 ppb in less than 20 minutes.

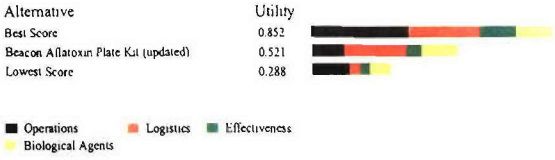
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Beacon Aflatoxin Plate Kit ranked in the bottom third of all evaluated products for analytical laboratories and earned 40% of the utility points of the best score.

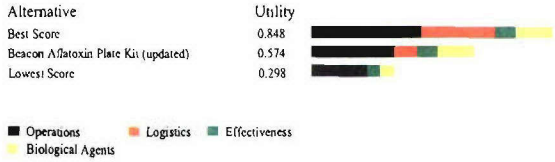
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Beacon Aflatoxin Plate Kit ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.

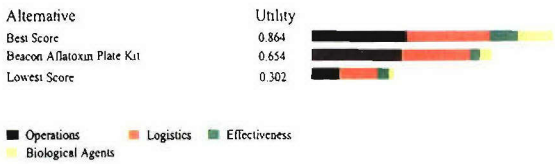
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Beacon Aflatoxin Plate Kit ranked in the middle third of all evaluated products for mobile laboratories and earned 68% of the utility points of the best score.

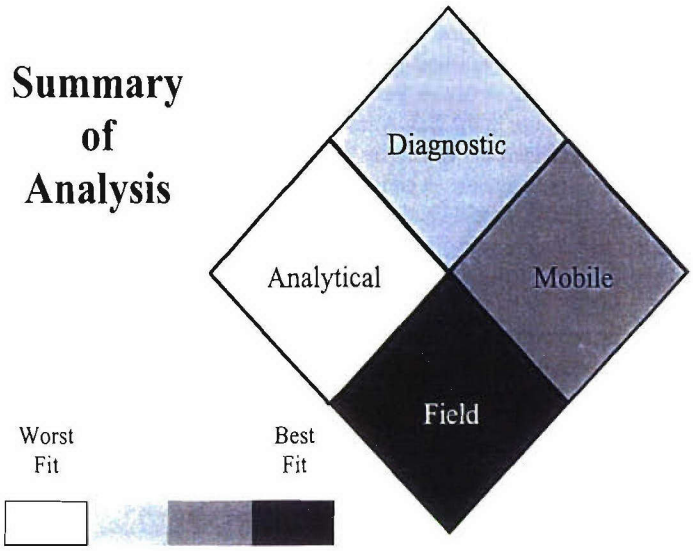
Field Use Ranking



Preference Set = Field Use

Beacon Aflatoxin Plate Kit ranked in the middle third of all evaluated products for field use and earned 76% of the utility points of the best score.

Summary of Analysis



Beacon Aflatoxin Plate Kit Evaluation Criteria Provided by Vendor

Sensitivity:
- NA CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 5-10 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Less than once a year service required
- Expected life is 3-5 years
- 10-20 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- Single shaking or vortexing step
- System able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

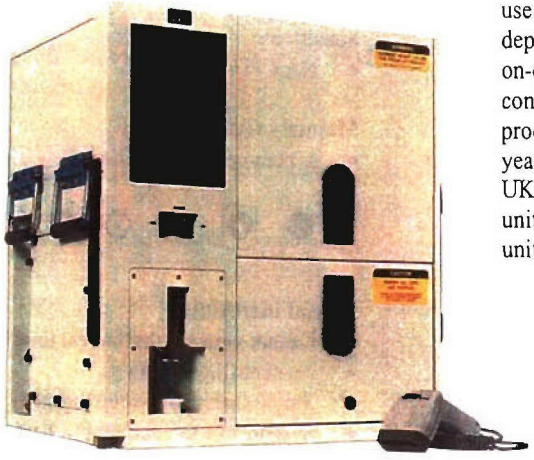
Cost: Approx. $3.00/sample
$240.00/96 test system or device

Beacon Analytical Systems, Inc.
383 Presumpscot St.
Portland, ME 04103
www.beaconkits.com

Point of Contact: Brian Skoczenski
(207) 761-2199
fax. (207) 761-9238
brians@beaconkits.com

Bio Detector (BD)

by Smiths Detection



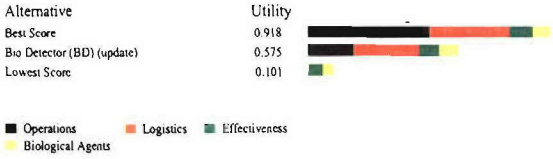
Description: The Biological Detector (BD) was jointly developed and field-tested by Smiths Detection – Edgewood (formerly Environmental Technologies Group, Inc.) and the U.S. Army for use in the U.S. Army's BIDS. The BD simultaneously detects up to eight different biological agents. Additional assays have been developed and validated for use for the BD and can be easily "swapped" depending on the intelligence. The BD is an on-demand, portable, system, or can run continuously for 14 hours. This is a mature product that has been in production for seven years. The BD has also been selected by the UK MoD for use in the IBDS. A total of 110 units have been fielded to date, and 42 more units will be manufactured for the UK.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (2)
Francisella tularensis (2)
Burkholdera mallei (1)
Burkholderia pseudomallei (2)
Yersinia pestis (2)
Coxiella burnetti (2)
Brucella species (2)
VEE virus (2)
Smallpox virus (2)
MS-2 bacteriophage (1)
Botulinum toxin A (2)
SEB (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The BD uses the principles of Immuno-ligand Assay (ILA) chemistries and the light-addressable potentiometric sensor (LAPS), licensed to Smiths by Molecular Devices Corporation, to specifically identify biological agents. The BD draws a one-milliliter liquid sample, which is segmented and specifically analyzed for eight different biological agents. The BD uses biotin and fluorescein labeled antibodies, and a tape cassette using biotin coated nitrocellulose membrane as the capture surface.

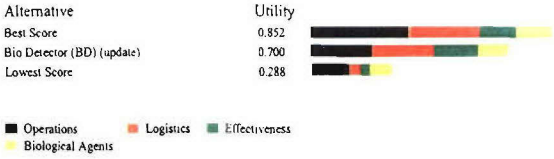
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Bio Detector ranked within the middle third of all evaluated products for analytical laboratories and earned 63% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

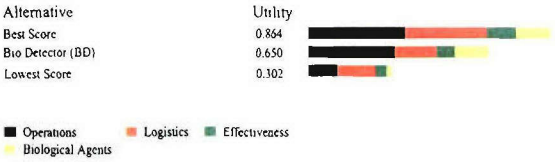
Bio Detector ranked in the top third of all evaluated products for diagnostic laboratories and earned 82% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

Bio Detector ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.

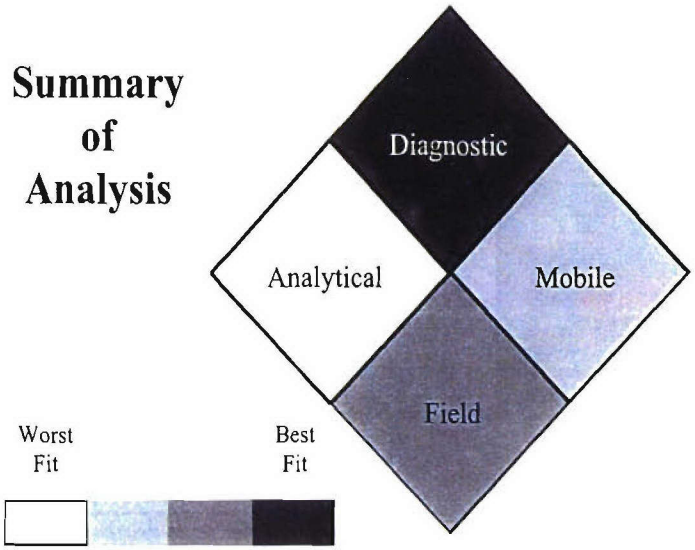
Field Use Ranking



Preference Set = Field Use

Bio Detector ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.

Summary of Analysis



Bio Detector (BD) Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 3 components
- Unit comes with a cleaning kit

Maintenance:
- 0-1 consumable or expendable needed
- No service required
- Expected life is 5-10 years
- 10-20 min required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Can only be operated at 25°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $4.78/sample
$225,000.00/system or device

Smiths Detection-Edgewood
2202 Lakeside Blvd.
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact: Keith Uithoven
(410) 510-9263 ext. 263
fax. (410) 510-9496
keith.uithoven@smithsdetection.com

Bio Threat Alert Tests Strips

by Tetracore Inc. and Alexeter Technologies

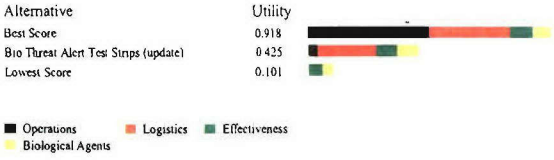
Description: The *Bio Threat Alert* is intended for biological agent screening in environmental samples. The *Bio Threat Alert Test Strip* is designed for both field and laboratory use but is ***not intended for use on clinical samples.***

Technology: The *BioThreat Alert* Test Strip from Tetracore, Inc is a lateral flow immunochromatographic device that uses two antibodies in combination to specifically detect anthrax in solution. One of the specific antibodies is labeled with a colloidal gold derivative. When sufficient target material is present, the colloidal gold label provides a reddish-brown colored line that is visualized after accumulating in the test sample region on the device. When a sample is added to the *BioThreat Alert* Test Strip, the sample begins to mix with the colloidal gold-labeled antibody and simultaneously moves along the strip membrane by capillary action. In the sample region of the test strip, if target is present, the second specific antibody captures the colloidal gold-labeled antibody and bound target, forming a colored line or band in the "S" window of the test strip. As an internal control, a second band visualized in the control ("C") window of the test strip is an indication that the test strip functioned properly. Two bands or colored lines (in the "S" and "C" windows) are required for a positive result determination.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (3)
Francisella tularensis (3)
Yersinia pestis (3)
Brucella species (3)
Orthopox virus (3)
Botulinum toxins A, B (3)
SEB (3)
Ricin (3)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

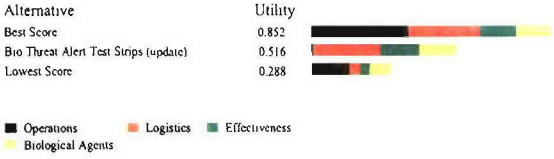
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Bio Threat Alert Test Strips ranked in the bottom third of all evaluated products for analytical laboratories an earned 46% of the utility points of the best score.

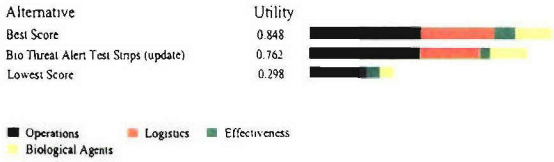
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Bio Threat Alert Test Strips ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 61% of the utility points of the best score.

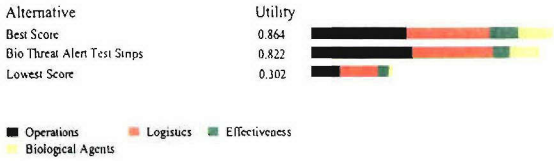
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Bio Threat Alert Test Strips ranked in the top third of all evaluated products for mobile laboratories and earned 90% of the utility points of the best score.

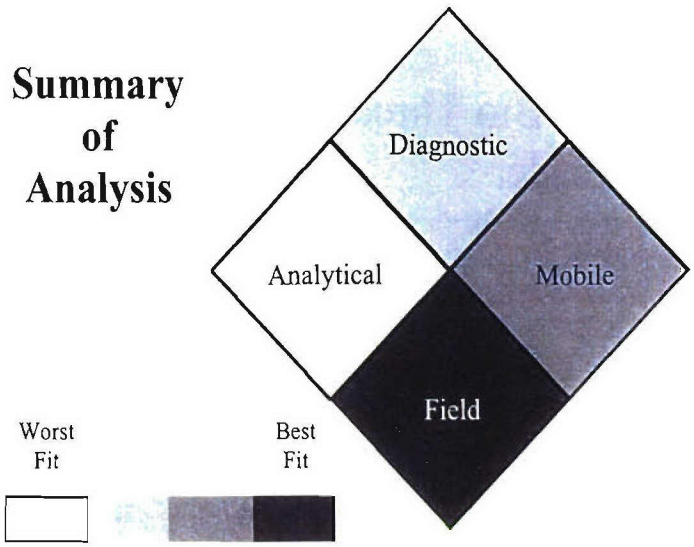
Field Use Ranking



Preference Set = Field Use

Bio Threat Alert Test Strips ranked in the top third of all evaluated products for field use and earned 95% of the utility points of the best score.

Summary of Analysis



Bio Threat Alert Tests Strips Evaluation Criteria Provided by Vendor

Sensitivity:
- Greater than 100,000 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device does not require electricity
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system designed for single use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components can be stored at 25°C to 45°C
- Performance not influenced by relative humidity

Cost: $25.00/sample
$25.00/system or device

Tetracore, Inc.
11 Firstfield Road
Gaithersburg, MD 20878
www.tetracore.com

Alexeter Technologies
830 Seton Court, Suite 6
Wheeling, IL 60090
www.alexeter.com

Points of Contact:

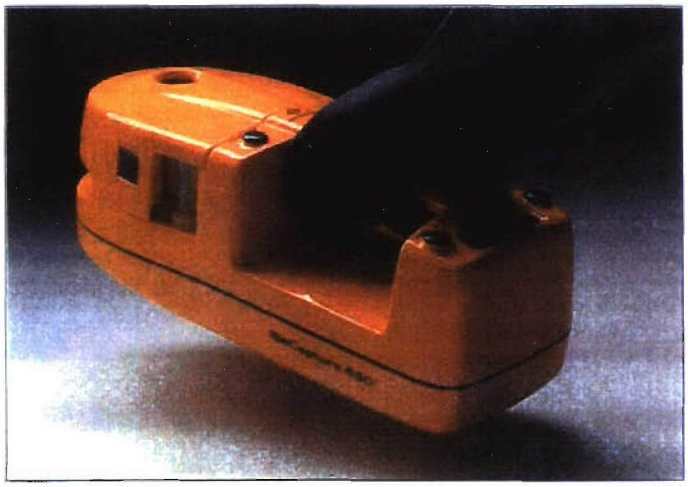
Tetracore
Tom O'Brien
(301) 258-7553
fax. (301) 258-9740
tobrien@tetracore.com

Alexeter
Jim Whelan
(847) 419-1507
fax. (847) 419-1648
jwhelan@alexeter.com

Additional Information:
Air Sample Collector Used With the Bio Threat Alert Test and Guardian Reader

BioCapture

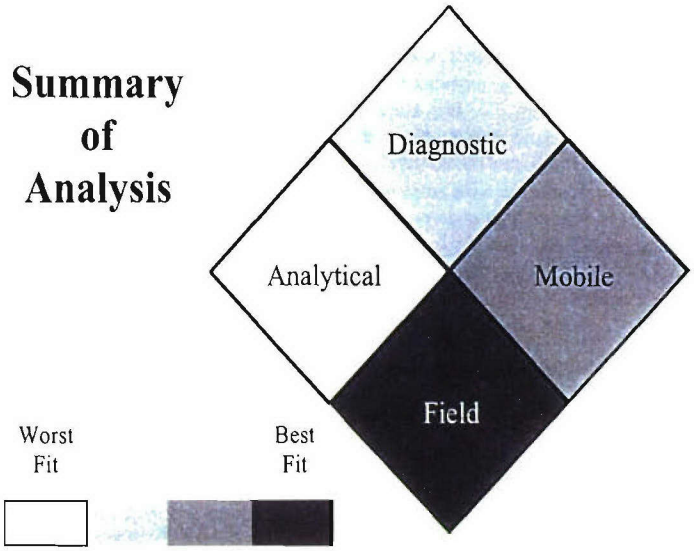
by MesoSystems



Description: The BioCapture 650 is cutting edge air sampling technology designed to collect airborne bioterrorism agents. Packed in a rugged 7.5 lb package, BioCapture 650 directly addresses the need for an air sampling product with laboratory performance in a field-deployable package.

Technology: The BioCapture product family is a series of biological samplers based on MesoSystems' patented rotating impactor technology. Aerosol particles are impacted onto a disk, separating them from the air stream. The particles are then rinsed off and become part of the sample that is tested for bio or chemical hazards. The sample is sent to the lab now but in the future, tests will be performed using test strips that are part of the BioCapture.

Summary of Analysis



BioCapture Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- NA sample detection
- NA samples/batch or higher
- NA volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief training
- No set-up required
- NA manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- NA solutions or buffers used
- 1 components
- No cleaning required

Maintenance:
- NA consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life is between 1-3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at room temperature
- Performance not influenced by relative humidity

Cost: $8,400.00/system or device

MesoSystems
1001 Menaul Blvd. NE Suite A
Albuquerque, NM 87107
www.mesosystems.com

Point of Contact: Julie Bazzell
(877) 692-2120
fax. (509) 222-2037
sales@mesosystems.com

Bio-Alloy 'Smart' Material Sensor

by IatroQuest Corporation

Description: IatroQuest Corporation's breakthrough, patented platform technology called Bio-Alloy, supports the development of a new and cost-effective approach to biosensing. Bio-Alloy technology converges biotechnology, nanotechnology, advanced semiconductor materials and photonics to create "smart materials." Unique attributes enable these materials to detect and identify, in a label-free and real-time manner, a wide range of biological agents as well as specific toxic chemical agents, with a high degree of sensitivity and selectivity. Applications in point and stand-off detection for biodefense are the primary focus with follow-on applications in medical diagnostics, environmental and life science sectors.

Able to Detect the Following Organisms/Toxins:
MS-2 bacteriophage (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The Bio-Alloy sensing technology platform combines elements of nanotechnology, advanced semiconductor materials, biotechnology and photonics to generate 'smart materials' with unique biosensing attributes. These advanced materials are produced in four steps: 1) *Silicon chip preparation*: dicing silicon chips to provide the basic material for Bio- Alloy 2) *Nanostructuring*: chemically treating silicon chips to produce nanostructured, photoluminescent, materials (feature size 2 – 3 nanometers), 3) *Surface chemistry*: attachment of linker molecules (required to attach biorecognition moieties), and 4) *Bioprocessing*: immobilizing specific recognition elements (e.g. antibody fragments, enzymes, sDNA) to produce specific biosensing capability. The underlying detection principle, based on a unique photoluminescence (green light emission) response generated directly by the Bio-Alloy material, relies on quantum confinement and changes in the surface energy when the surface is excited with low-power blue light (micro-Watt LED; 1 second integration time). Affinity binding of target agents to recognition elements linked to the Bio-Alloy surface causes *perturbations* in the surface energy states / photoluminescence response detected as an increase in light intensity.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Bio-Alloy Smart Material Sensor (new)	0.587
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

Bio-Alloy ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Bio-Alloy Smart Material Sensor (new)	0.672
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

Bio-Alloy ranked in the middle third of all evaluated products for diagnostic laboratories and earned 79% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Bio-Alloy Smart Material Sensor (new)	0.549
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

Bio-Alloy ranked in the middle third of all evaluated products for mobile laboratories and earned 65% of the utility points of the best score.

Field Use Ranking

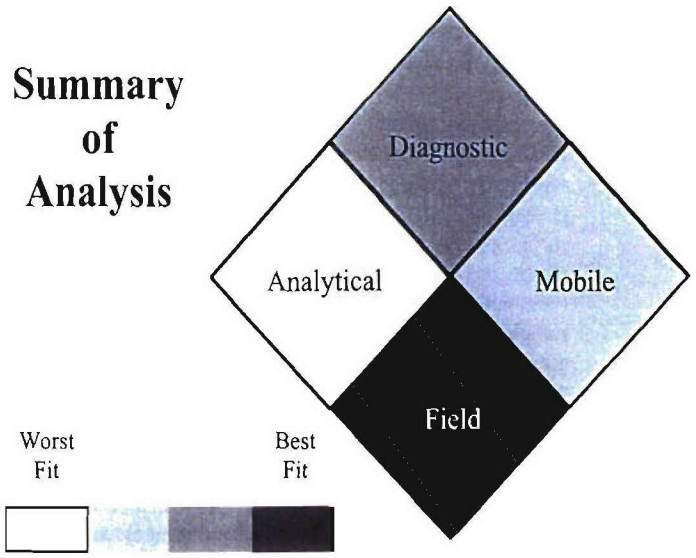
Alternative	Utility
Best Score	0.864
Bio-Alloy Smart Material Sensor	0.687
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

Bio-Alloy ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.

Summary of Analysis



Bio-Alloy 'Smart' Material Sensor

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within two calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device uses batteries
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 1 components
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Needs service every 6 months
- Expected life measure unknown
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 6 months-1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System may be capable of interpreting raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

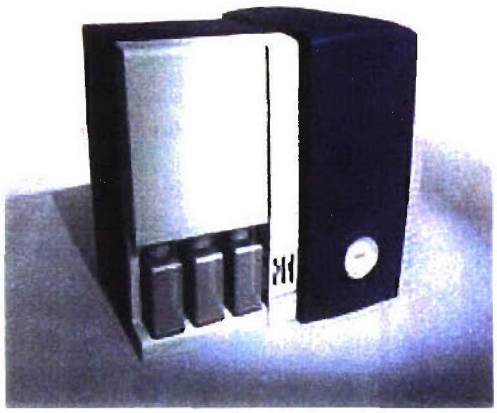
Cost: $0.5-$1.00/sample
$10,000/device or system

IatroQuest Corporation
309-2183 Ogilvie Rd
Ottawa, Ontario K1J 1C8
www.IatroQuest.com

Point of Contact: David Armstrong
(613) 990-0864
(613) 991-3843 fax
darmstrong@iatroquest.com

BIODET-400 Laboratory Instrument

by Ciencia Inc.

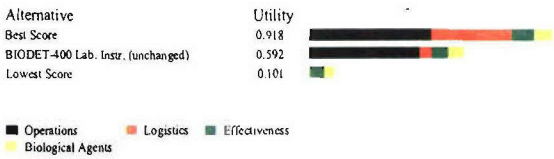


Description: The *BIODET-400* system provides the capability for rapid, highly multiplexed detection of biological pathogens and toxins. It uses on-chip immunoassay technology with a novel evanescent wave sensing method that enables label-free detection with high sensitivity. The evanescent wave is created either via grating-coupled surface waveguides or via grating-coupled surface plasmon resonance (GCSPR). The chip (1 cm^2) is plastic, has an impressed grating, and surface chemistry for immobilizing antibodies (up to 400 spots per chip). The sample to be analyzed (in liquid form) is caused to flow over the chip, either with microchannels and a manifold for multiple inputs, or uniformly for a single input. Readout is accomplished with a beam of NIR light produced by an LED and imaging detection is performed with CCD camera, whereby changes in the index of refraction at all antibody sites are simultaneously measured. Since no labels are required (fluorescent, enzymatic, chemiluminescent, etc.) samples can be processed directly with minimal or no preparation. The system can potentially be configured as an on-line, real-time continuous monitor, a laboratory instrument, or a hand-held portable device.

Technology: Appropriate antibodies are immobilized in array format on the chip, either at manufacture or in the field using unique self-assembly methods. A manifold assembly houses necessary buffers. Sample is introduced to manifold and pumped across sensor chip. Manifold, chip, and pump parts are disposable. Microarray includes up to 400 spots, for simultaneous detection of up to 100 or more analytes (in duplicate or triplicate plus reference spots). Sensitivity is ~ 1 pg/mm^2. We estimate that sensitivity is sufficient for detection of single spores of *Bacillus anthracis*.

No Formal Detection Assays Availble

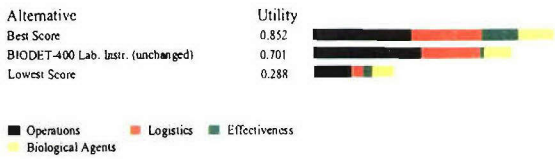
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

BIODET-400 Laboratory Instrument ranked in the middle third of all evaluated products for analytical laboratories and earned 64% of the utility points of the best score.

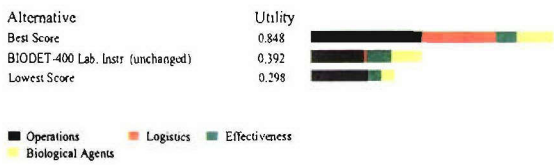
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

BIODET-400 Laboratory Instrument ranked in the top third of all evaluated products for diagnostic laboratories and earned 82% of the utility points of the best score.

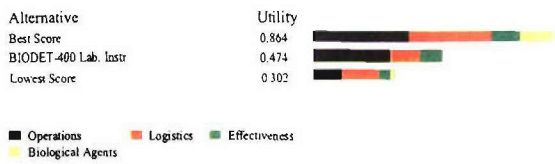
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

BIODET-400 Laboratory Instrument ranked in the bottom third of all evaluated products for mobile laboratories and earned 46% of the utility points of the best score.

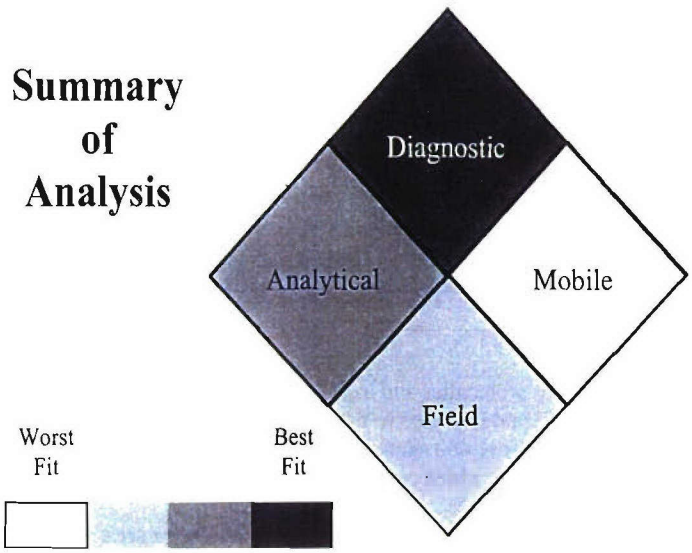
Field Use Ranking



Preference Set = Field Use

BIODET-400 Laboratory Instrument ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.

Summary of Analysis



BIODET-400 Laboratory Instrument Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 sample/batch
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- A day of training
- 5-10 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Needs service once a year
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $50.00/sample
$40,000.00/system or device

Ciencia Inc.
111 Roberts St., Suite K
East Hartford, CT 06108
www.ciencia.com

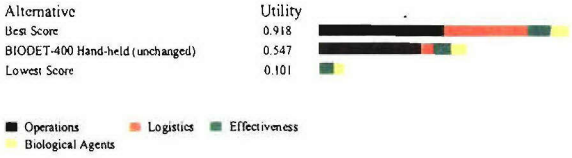
Point of Contact: S. Fernandez, Ph.D.
(860) 528-9737
fax. (860) 528-5658
Fernandez@ciencia.com

Additional Information:

BIODET-400 Hand-held Portable Device

CLARIFYING COMMENTS:
The technology and instrument described have been developed for proteomics and high throughput screening applications. Target proteins are fixed on the chip (see #1 above) surface, and liquid is caused to flow over this surface. In this manner, data on binding kinetics is rapidly collected for protein arrays of sizes of 400 spots. The detection method does not require the use of labels (such as fluorescent, enzymatic or chemiluminescent), which results in very simple protocols and rapid detection.
In the past year, this instrument has been evaluated for on-chip immunoassay purposes, and found to be of great value in terms of sensitivity, array format, speed, and versatility. A number of applications are being developed at Ciencia for NASA and NIH (National Institutes of Health). These include bioreactor product monitoring in space, phenotyping of animal models and other proteomics applications. Ciencia recently received a grant from the National Science Foundation to explore the use of this system for detection of environmental pathogens. Our results thus far indicate that this system would provide powerful technology for rapid detection of biological agents, both in the laboratory and the field. Based on the results of this year's work, Ciencia intends to produce and market the instrument for bio-agent detection as well as pathogen detection, in general. Development is required to design apparatus to insert collected samples in the chip buffer compartments, the channels themselves, and the specific assays. A summary of position might show that an immunoassay system was 85% developed with 15% remaining. Ciencia is seeking interested partners and funding to accelerate this final stage of development. Partners may have assays, may want to manufacture disposable components, or may be interested in equity (or other) funding arrangements.

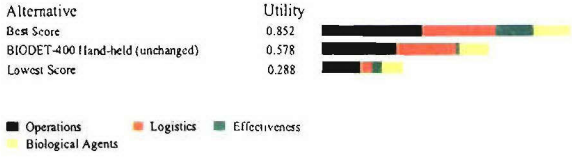
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

BIODET-400 Hand-held Portable Device ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

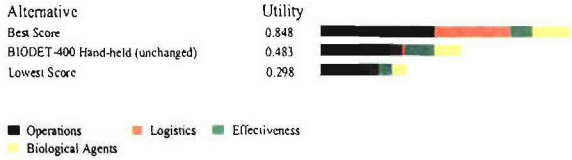
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

BIODET-400 Hand-held Portable Device ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.

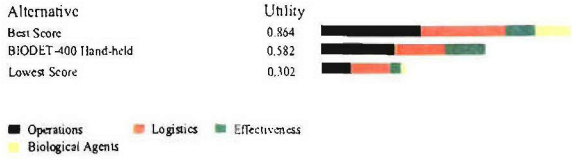
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

BIODET-400 Hand-held Portable Device ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.

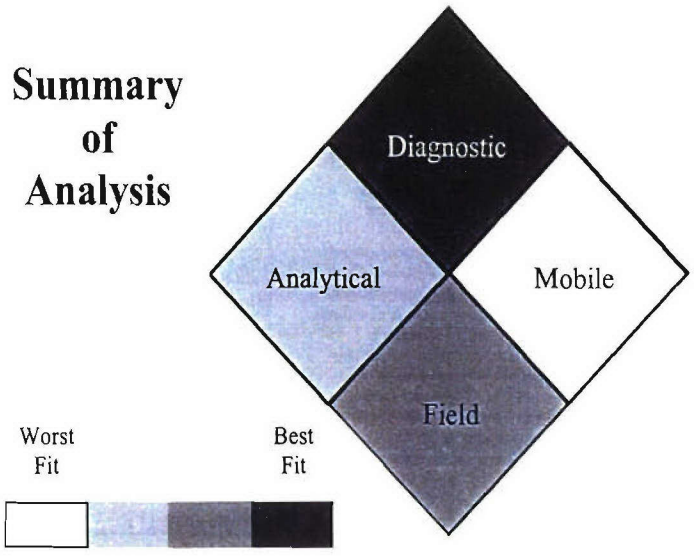
Field Use Ranking



Preference Set = Field Use

BIODET-400 Hand-held Portable Device ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

Summary of Analysis



BIODET-400 Hand-held Portable Device Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- There is a single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 sample/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device is not amendable to automation

Training/Speed/Manpower:
- A day of training
- 5-10 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Estimated once a year service required
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $50.00/sample
$40,000.00/system or device

Ciencia Inc.
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East Hartford, CT 06108
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Point of Contact: S. Fernandez, Ph.D
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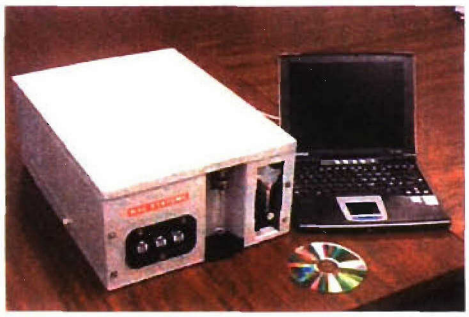
Fernandez@ciencia.com

BioMAPP

by BAE Systems



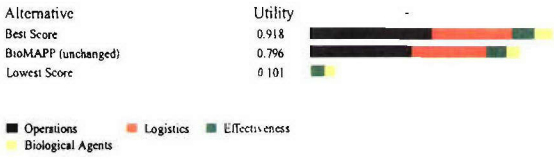
Description: The BioMAPP (Biological Multi-Analyte Pathogen Profiler) Detection System has the ability to perform a wide range of assays, including nucleic acid assays for both DNA and RNA and immunoassays. It also allows assays for antibodies in clinical samples that indicate prior exposure to a BW agent, even if that agent is no longer present in the sample. This is a capability absent in systems that rely solely on nucleic acid detection assays. The BioMAPP system can interrogate a single 10-20 uL sample for up to 100 different analytes/agents and controls, simultaneously. This large capacity not only allows testing for multiple targets at once, it also allows rejection of near neighbors, permits differentiation of target strains, and supports inclusion of controls. In addition, the system allows for the identification of multiple targets for each agent. This redundant identification of each agent essentially eliminates false positive and false negative samples. To help reduce logistic support requirements, the BioMAPP uses clinical or environmental sample sizes as small as 10-20 uL. Once a processed sample has been added to the device, detection and agent identification are completed in a matter of seconds. An optional separate device (XY Platform) allows automated assays of 96 different samples (again, with up to 100 assays performed on each sample). A high-throughput version also exists, that can perform nearly one-half million assays per day. Thus, a great many sample assays can be performed without needing a large number of analyzers; one device can do the work of many.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli 0157:H7 (1)
Francisella tularensis (1)
Vibrio cholera (1)
Burkholderia mallei (1)
Yersinia pestis (1)
Coxiella burnetti (1)
Brucella species (1)
Rift Valley fever virus (1)
Venezuelan Equine Encephalitis virus (1)
Hanta virus (1)
Yellow fever virus (1)
Dengue fever virus (1)
Orthopox virus (1)
MS-2 bacteriophage (1)
Botulinum toxins A,B,E (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: With xMAP technology, molecular reactions take place on the surface of microscopic beads called microspheres. For each reaction in a xMAP profile, thousands of molecules are attached to the surface of internally color-coded microspheres. The assigned color-code identifies the reaction throughout the test. The magnitude of the biomolecular reaction is measured using a second molecule called a reporter. The reporter molecule signals the extent of the reaction by attaching to the molecules on the microspheres. Because the reporter's signal is also a color, there are two sources of color, the color-code inside the microsphere and the reporter color on the surface of the microsphere. To perform a test, the color-coded microspheres, reporter molecules, and sample are combined. This mixture is then injected into an instrument that uses microfluidics to align the microspheres in single file where lasers illuminate the colors inside and on the surface of each microsphere. Next, advanced optics capture the color signals. Finally, digital signal processing translates the signals into real-time, quantitative data for each reaction. The BioMAPP utilizes xMAP technology which enables simultaneously assay detection up to 100 analytes in a single well of a microtiter plate, using very small sample volumes. The system delivers fast and cost-effective bioassay results on many assay formats including nucleic acid assays, receptor-ligand assays, immunoassays and enzymatic assays.

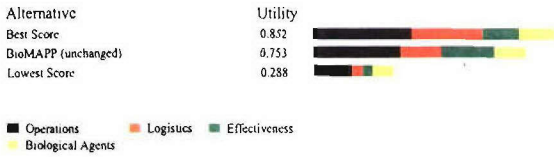
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

BioMAPP ranked in the top third of all evaluated products for analytical laboratories and earned 87% of the utility points of the best score.

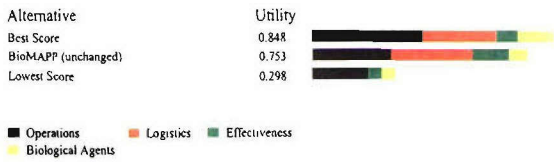
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

BioMAPP ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.

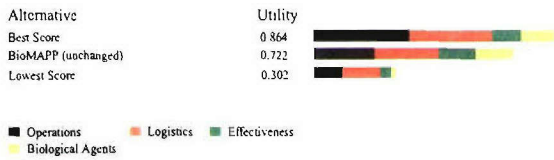
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

BioMAPP ranked in the top third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

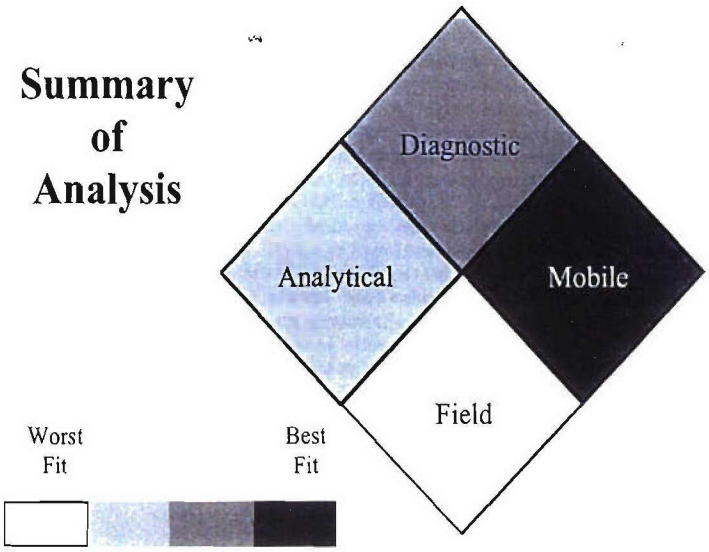
Field Use Ranking



Preference Set = Field Use

BioMAPP ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

Summary of Analysis



BioMAPP Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has a 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:
- A day of training
- Greater than 20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- Daily washing with water required

Maintenance:
- 3 consumables or expendables needed
- Every 6 months service required
- Expected life is greater than 10 years
- Less than 5 minutes of daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- Multiple centrifugation steps
- A single shaking or vortexing step
- System is sometimes able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- Four additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at 25°C to 37°C
- Device or system has peak performance at normal relative humidity conditions only

Cost: $1.84/sample
$70,000.00/system or device

BAE Systems, Inc.
Integrated Defense Solutions
Austin, TX 78725
Woodinville, Washington 98072
www.baesystems.com

Point of Contact: Gary Morris
(512) 926-2800
fax. (512) 929-4774
gary.k.morris@baesystems.com

Bio-Seeq

by Smiths Detection

Description: There is a growing need for portable, battery-powered instruments capable of detecting and identifying biological agents that may be used against military and civilian targets. The Bio-Seeq detection system, developed by Smiths Detection, is designed to address this need. The instrument weighs 6.5lbs, processes up to six samples at one time, and will operate for up to 2.5 hours with a rechargeable battery. Two independent optical channels allow the simultaneous detection of an agent of interest along with an internal positive control to verify that the sample was correctly processed. The ease of sample preparation and reagent handling is a key component in reliably performing PCR assays. The consumable developed by Smiths Detection is complete and self-contained with all necessary reagents, filtering, and reconstitution fluids. Processing of the assay involves a simple wipe of the target powder followed by a simple rotating action and then shaking on the part of the operator. No pipetting or other fluid transfer is required to complete a test. The amplification of the sample is performed by the instrument and results in an indication of positive, negative, or indeterminate is displayed for samples that have been inhibited by an environmental substance. Positive samples have cycle time or CT number that indicate the approximate concentration. Test results and data are stored in non-volatile EEPROM for later retrieval using PC based software. Processing time for most reagents is less than 40 minutes. Tests with anthrax samples have shown that detection limits as low as 125 CFU's per test were reliably detected. The instrument is currently available with a menu of Anthrax and Tularemia. Plague and SmallPox will be planned.

Able to Detect the Following Organisms:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (2)
Smallpox virus (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Polymerase Chain Reaction technology is a well known and researched technology used to rapidly identify a potential threat agent by its unique DNA. Six independently controlled thermocyclers are used to process real time Taqman assays. Detection of amplification products uses fluorescent-labeled probes designed for a specific agent of interest. Dual light paths allow the simultaneous detection of two different fluorescent probes during the amplification process. The speed, small size, and low power of the thermocycler is what makes the Bio-Seeq unique in the field of portable DNA detection.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Bio-Seeq Thermocycler (update)	0.656
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

Bio-Seeq ranked in the middle third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Bio-Seeq Thermocycler (update)	0.709
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

Bio-Seeq ranked in the top third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Bio-Seeq Thermocycler (update)	0.673
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

Bio-Seeq ranked in the top third of all evaluated products for mobile laboratories and earned 79% of the utility points of the best score.

Field Use Ranking

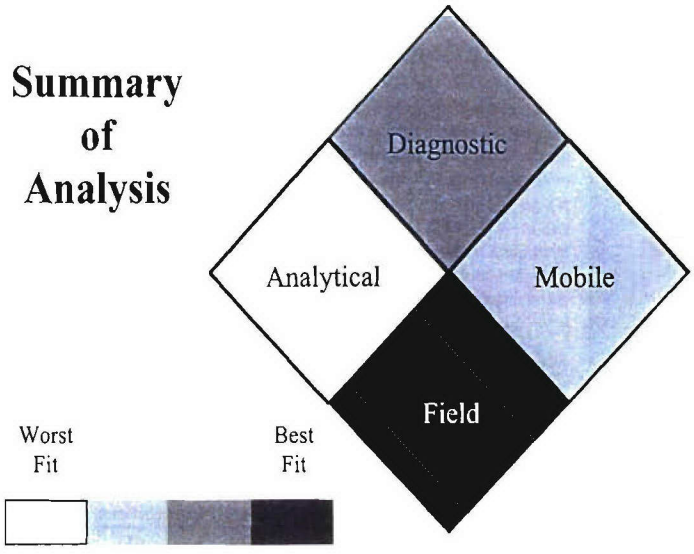
Alternative	Utility
Best Score	0.864
Bio-Seeq Thermocycler	0.749
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

Bio-Seeq ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

Summary of Analysis



Bio-Seeq Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- A single shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

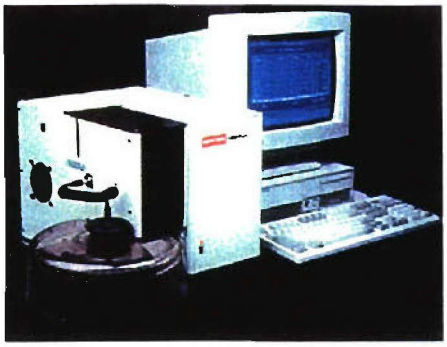
Cost: $30.00/sample
Approximately $30,000.00/system or device

Smiths Detection
2202 Lakeside Blvd.
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact: Doug Green
(410) 510-9209
fax. (410) 510-9496
doug.green@smithsdetection.com

BioVeris (BV) Detection System

by BioVeris Corp.



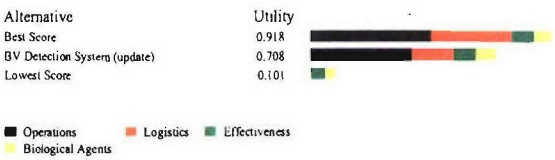
Description: The BV Detection System is an automated analyzer designed for use with BV reagents. This system provides sample handling, detection based upon BioVeris (BV) Technology, electrochemiluminescence, and analysis in a 50 tube carousel-based format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about 1 minute and an entire carousel in less than an hour. It can also run a partial or an entire carousel in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (4)
E. coli 0157:H7 (3)
Francisella tularensis (4)
Yersinia pestis (4)
Smallpox virus (4)
Orthopox virus (4)
Botulinum toxins A,B,E (4)
SEB (4)
Ricin (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG, the product name for ruthenium (II) tris-bipyridine. Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, oligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagenetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

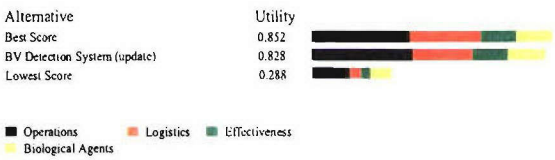
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

BV Detection System ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

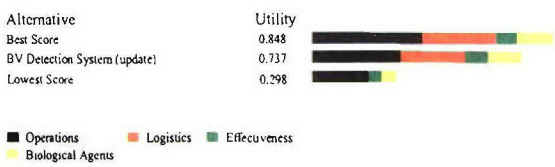
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

BV Detection System ranked in the top third of all evaluated products for diagnostic laboratories and earned 97% of the utility points of the best score.

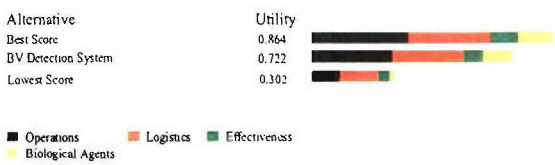
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

BV Detection System ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.

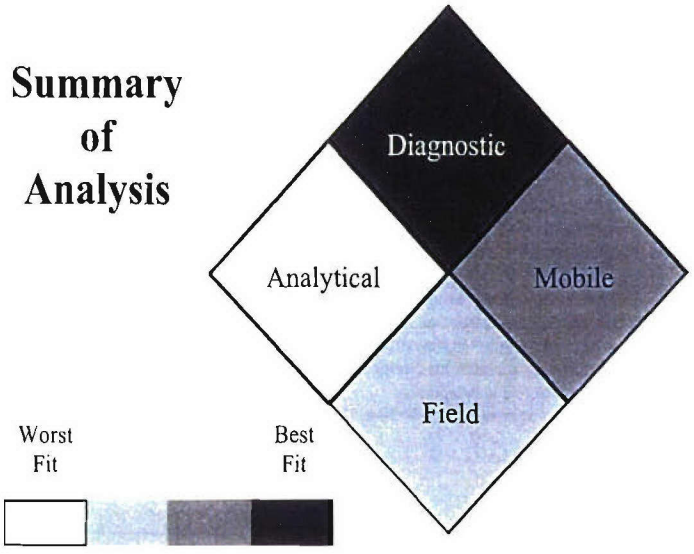
Field Use Ranking



Preference Set = Field Use

BV Detection System ranked in the top third of all evaluated products for field use and earned 84% of the utility points of the best score.

Summary of Analysis



BioVeris Detection System Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

Reagents available from the Critical Reagents Program. Call 410-436-5562 for more information.

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffer used
- 1 component
- A decontamination protocol is required for use one time per week

Maintenance:
- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

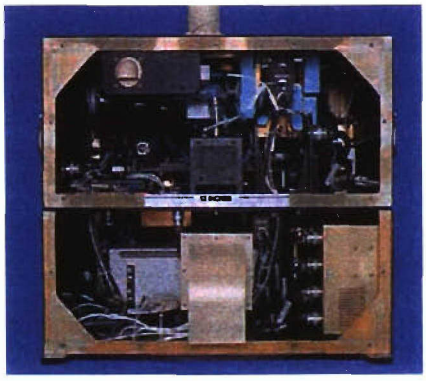
Cost: $<10.00/sample
$42,604.00/system or device

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, MD 20877
www.bioveris.com

Point of Contact: Jill White
(301) 869-9800 ext. 1054
fax. (240) 632-2206
jwhite@bioveris.com

CANARY Biosensor: Four-channel Automated Bioaerosol Sensor

by MIT Lincoln Laboratory



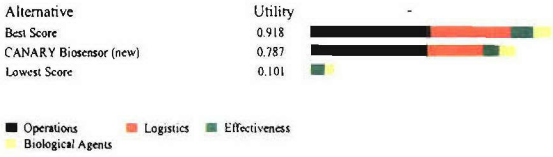
Description: CANARY is a cell-based biosensor technology that has demonstrated a unique combination of speed and sensitivity for pathogen identification in a wide range of sample types including bioaerosol samples, clinical samples, surface wipes, and food. CANARY tests are simple, use few consumables, and can be performed in small, lightweight equipment that is compatible with battery power for field use. CANARY tests can be as simple as adding a drop of cells to a sample (e.g. dry-impacted bioaerosol samples) and placing the mixture in a luminometer to detect antigen-specific light generation in less than one minute. For maximum sensitivity in complex liquid samples, brief spins are incorporated into a procedure that can provide identification in 3 minutes after sample collection.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli O157:H7 (1)
Francisella tularensis (1)
Vibrio cholera (1)
Yersinia pestis (1)
Brucella species (1)
Smallpox virus (1)
VEE virus (1)
Dengue fever virus (1)
Orthopox virus (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: CANARY utilizes B cells that have been genetically engineered to produce aequorin, a calcium-sensitive bioluminescent protein originally found in the Aequorea victoria jellyfish. The sensor works as follows: (1) The B cells can be exposed to suspected bioagents or other pathogens from an air sample or other source. (2) The B cells produce antibodies specific for certain bioagents. If one of those agents is present in the sample, it will bind to the antibodies on the surface of the B cell. (3) Crosslinking of a B cell's antibodies by a bioagent triggers an intracellular enzymatic cascade that releases calcium inside the cell. (4) In the presence of calcium, the aequorin emits blue-green light at 469 nm within seconds of antigen-specific crosslinking. (5) Light from stimulated B cells can be detected using a photomultiplier tube or other photodetector. CANARY can currently identify 13 different bacterial and viral agents including *Bacillus anthracis* spores, *Yersinia pestis*, *Francisella tularensis*, and vaccinia (for a complete listing see Table 1 below), and development is underway to enable toxin identification.

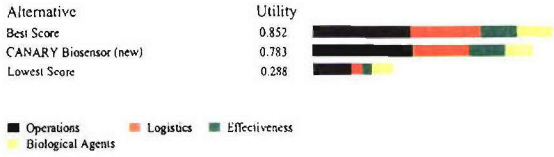
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

CANARY ranked in the top third of all evaluated products for analytical laboratories and earned 86% of the utility points of the best score.

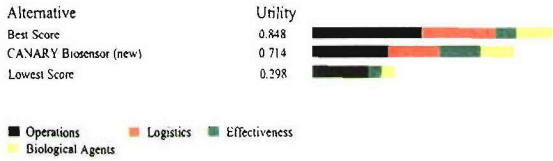
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

CANARY ranked in the top third of all evaluated products for diagnostic laboratories and earned 92% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

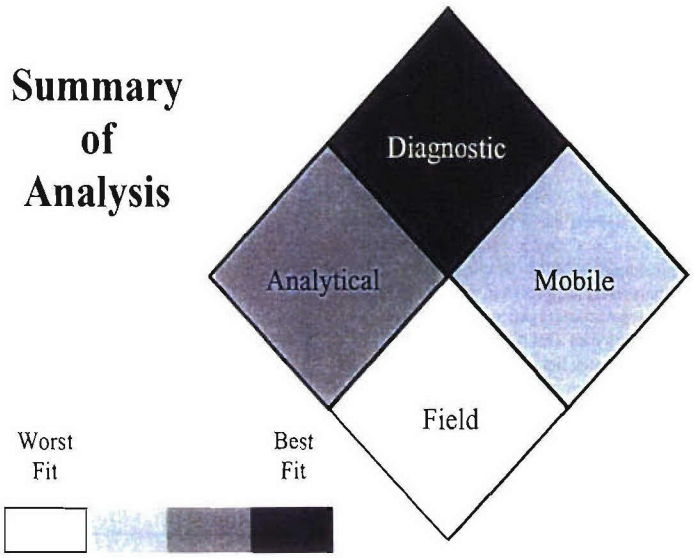
CANARY ranked in the top third of all evaluated products for mobile laboratories and earned 84% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

CANARY ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

Summary of Analysis



CANARY Biosensor: Four-channel Automated Bioaerosol Sensor Evaluation Criteria Provided by Vendor

Sensitivity:
- CFU per ml is not applicable

Maturity Gauge:
- Expected to be ready for commercialization within three or more calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device requires no water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- More than a day of training
- 5-10 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 5 or more consumable or expendable needed
- Needs service more often than every 6 months
- Expected life measure of greater than 10 years
- 5-10 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Can view results "in real time"
- A single centrifugation step
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at 4°C to 37°C
- Performance of the device or system is not influenced by relative humidity

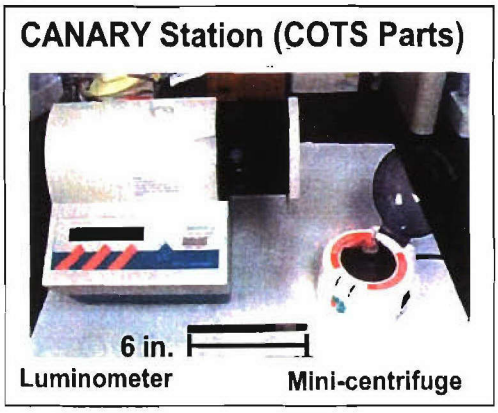
Cost: Approximately $0.50/sample
>$100,000/device or system

MIT Lincoln Laboratory
244 Wood St.
Lexington, MA 02420

Point of Contact: Mark A. Hollis
(781) 981-7840
(781) 981-3867 fax
hollis@ll.mit.edu

CANARY Biosensor: Manually operated portable instrument

by MIT Lincoln Laboratory



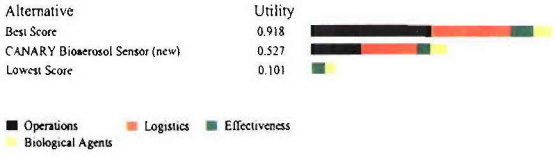
Description: CANARY is a cell-based biosensor technology that has demonstrated a unique combination of speed and sensitivity for pathogen identification in a wide range of sample types including bioaerosol samples, clinical samples, surface wipes, and food. CANARY tests are simple, use few consumables, and can be performed in small, lightweight equipment that is compatible with battery power for field use. CANARY tests can be as simple as adding a drop of cells to a sample (e.g. dry-impacted bioaerosol samples) and placing the mixture in a luminometer to detect antigen-specific light generation in less than a minute. For maximum sensitivity in complex liquid samples, brief spins are incorporated into a procedure that can provide identification in 3 minutes after the sample is collected.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli O157:H7 (1)
Francisella tularensis (1)
Vibrio cholera (1)
Yersinia pestis (1)
Brucella species (1)
Smallpox virus (1)
VEE virus (1)
Dengue fever virus (1)
Orthopox virus (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: CANARY utilizes B cells that have been genetically engineered to produce aequorin, a calcium-sensitive bioluminescent protein originally found in the Aequorea victoria jellyfish. The sensor works as follows: (1) The B cells can be exposed to suspected bioagents or other pathogens from an air sample or other source. (2) The B cells produce antibodies specific for certain bioagents. If one of those agents is present in the sample, it will bind to the antibodies on the surface of the B cell. (3) Crosslinking of a B cell's antibodies by a bioagent triggers an intracellular enzymatic cascade that releases calcium inside the cell. (4) In the presence of calcium, the aequorin emits blue-green light at 469 nm within seconds of antigen-specific crosslinking. (5) Light from stimulated B cells can be detected using a photomultiplier tube or other photodetector. CANARY can currently identify 13 different bacterial and viral agents including Bacillus anthracis spores, Yersinia pestis, Francisella tularensis, and vaccinia, and development is underway to enable toxin identification.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

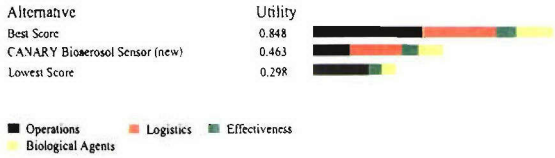
CANARY Biosensor ranked in the middle third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

CANARY Biosensor ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 65% of the utility points of the best score.

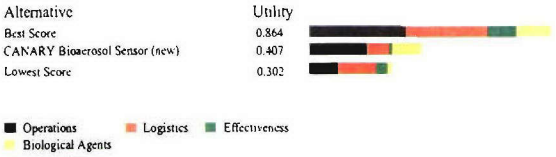
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

CANARY Biosensor ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.

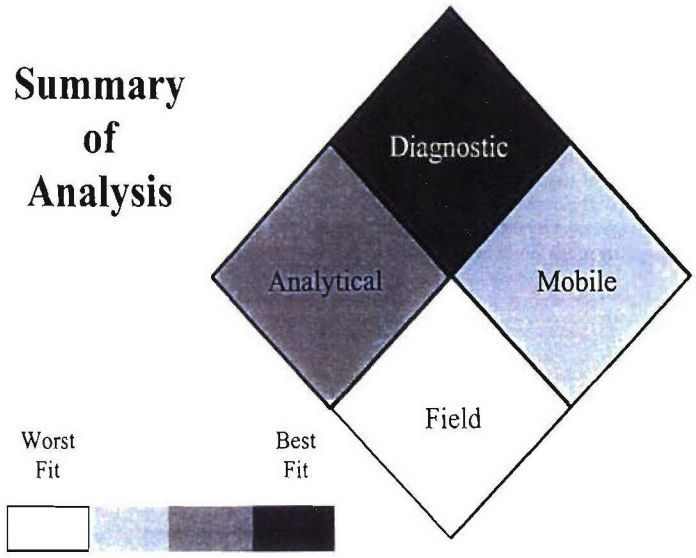
Field Use Ranking



Preference Set = Field Use

CANARY Biosensor ranked in the bottom third of all evaluated products for field use and earned 47% of the utility points of the best score.

Summary of Analysis



CANARY Biosensor: Four-channel Automated Bioaerosol Sensor Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device uses batteries
- The system or device requires no water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:
- A day of training required
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 2 solution or buffer used
- 4 components
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Never needs service
- Expected life measure of greater than 10 years
- 5-10 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage
- Between 1-5 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Can view results "in real time"
- Multiple centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: Approximately $0.25/sample
$6,000/device or system

MIT Lincoln Laboratory
244 Wood St.
Lexington, MA 02420

Point of Contact: Mark A. Hollis
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MSD Cartridge Reader

by Meso-Scale Discoveries

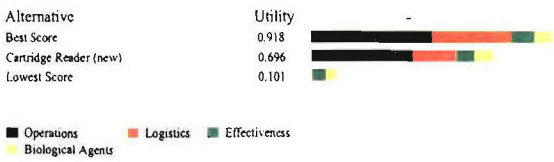
Description: The Cartridge Reader is an electrochemiluminescence (ECL) based, portable system with all assay reagents contained in a stand-alone cartridge. Just add sample to the cartridge and the system will do the rest. Cartridges are capable of performing up to 20 tests per sample. The instrument is capable of rapid, highly sensitive measurements and detecting multiple analytes (up to 20 tests per sample) in a single cartridge. The system is being designed for use in the clinical diagnostics market. On top of superior detection capabilities across the spectrum of potential bioagents (viruses, bacteria and toxins,) the MSD instrument is easy to use and capable of providing results in 15 minutes without any user intervention. The Cartridge Reader is perfectly suited for the needs the first responder or a soldier out in the field.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli O157:H7 (1)
Francisella tularensis (1)
Yersinia pestis (1)
VEE virus (1)
Botulinum toxin A (1)
SEB (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Electrochemiluminescence (ECL) is a well-developed, commercial technology for the detection and study of biomolecular interactions and function. ECL-based assays employ labels that emit light when electrochemically oxidized or reduced under appropriate chemical conditions. The existence of small, stable and highly efficient ECL labels makes the technique robust, sensitive and easy to implement. ECL detection is already widely used in the military for detection of biological agents. We have adapted the technology to allow ECL assays to be carried out on inexpensive disposable electrodes in a format that is compatible with multiplexed array-based measurements. Our systems are currently being evaluated at the Edgewood Chemical and Biological Center and USAMRIID. Assays are carried out on proprietary cartridges that have integrated electrodes that act as both a capture surface and an energy source for electrochemiluminescence excitation. The spatial control inherent in ECL induction and imaging detection allows for multiplexed array based measurement employing patterned arrays of binding reagents on an electrode surface. In addition, the cartridges contain all the necessary wet reagents to perform a measurement. Cartridges are capable of detecting up to 20 analytes per sample. The cartridges will be manufactured using well-established scalable techniques such as screen-printing that allow for high volume manufacturing at low cost. These assays are capable of highly sensitive detection with broad dynamic ranges. A cartridge can be read in under 15 minutes.

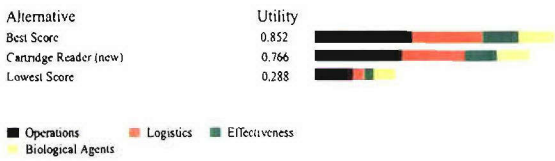
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

MSD Cartridge Reader ranked in the top third of all evaluated products for analytical laboratories and earned 76% of the utility points of the best score.

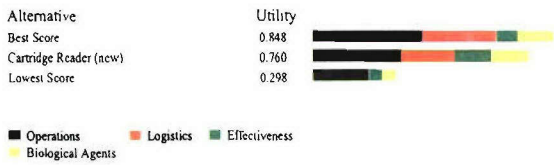
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

MSD Cartridge Reader ranked in the top third of all evaluated products for diagnostic laboratories and earned 90% of the utility points of the best score.

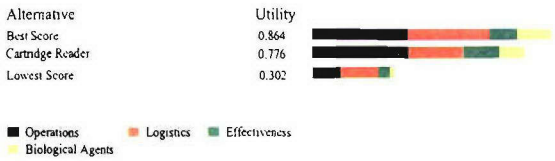
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

MSD Cartridge Reader ranked in the top third of all evaluated products for mobile laboratories and earned 90% of the utility points of the best score.

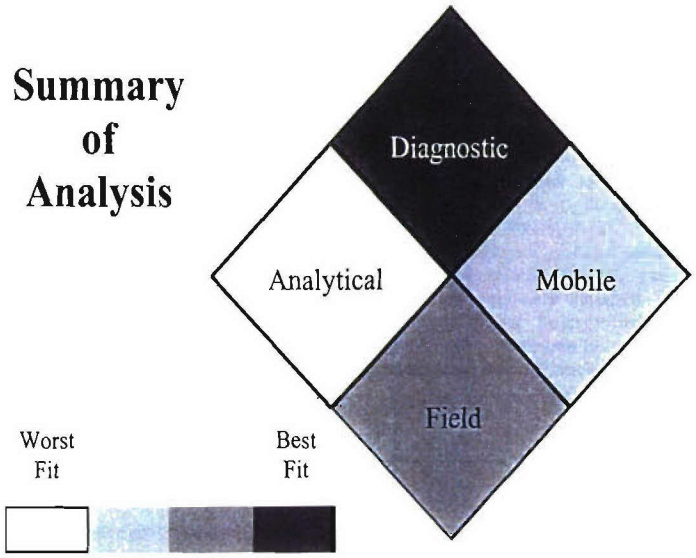
Field Use Ranking



Preference Set = Field Use

MSD Cartridge Reader ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.

Summary of Analysis



MSD Cartridge Reader

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within two calendar years
- Only one incomplete device or system exist (bread board)

System requirements:
- System or device uses batteries
- The system or device does not require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in less than 20 min
- 1 samples/batch
- Less than 50 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 1 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Needs service less than once a year
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a toaster
- Between 1-5 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at 25°C to 37°C
- Performance of the device or system is not influenced by relative humidity

Cost: To Be Determined/assay
To Be Determined/device or system

Meso-Scale Discoveries
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(240) 632-2219 fax
vvasista@meso-scale.com

ChemSensing Colorimetric Sensor

by ChemSensing, Inc.

Description: ChemSensing, Inc. (CSI) possesses a unique chemical detection technology in which colorimetric changes in an array of dyes constitute a signal much like that generated by the mammalian olfaction system; each dye is a cross-responsive sensor. This technology uses a disposable two-dimensional array of chemoresponsive dyes as the primary sensor elements, making it particularly suitable for detecting many of the odiferous compounds produced by microbiological agents. Striking visual identification of a wide range of volatile organic compounds (VOCs), including carboxylic acids, alcohols, amines, ethers, thioethers, and thiols, are easily made at *part per billion* (ppb) levels (i.e., sensitivities comparable to or better than gas chromatographic flame ionization (GC-FID) or mass spectrometric (GC-MS) detection). Our strategy toward detection of biological agents involves recognition and differentiation based on the volatile metabolites generated by a microorganism. Each species of organism emits a distinct profile of enzymatic reaction products in the form of VOCs, e.g., amines, sulfides or fatty acids. Based on cross-responsive sensor elements, this array records the composite responses unique to each microorganism. We envision this technology as having applications for real-time, portable, easy-to-use, commercial sensors for detection of pathogens and hazardous substances having applications in medicine, biotechnology, food safety, environmental monitoring, in addition to detection of chemical and biological warfare agents.

No Formal Detection Assays Available

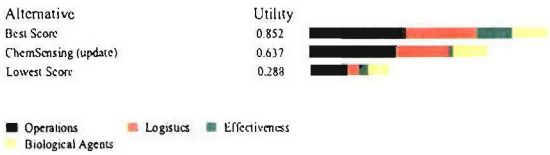
Technology: Metalloporphyrins are a natural choice for the detection of metal-ligating vapors because of their open coordination sites for axial ligation, their large spectral shifts upon ligand binding, and their intense coloration. CSI's technology takes advantage of the large color changes induced in metalloporphyrins upon ligand binding to create a simple colorimetric technique that minimizes the need for extensive signal transduction hardware. The large spectral changes (and readily observable color changes) that occur in solution during ligand binding to metalloporphyrins have been well documented. Furthermore, the periphery of the metalloporphyrin can be easily modified, thereby adjusting the accessibility of the metal ion to the ligand and inducing shape-selective ligation. Using metal centers that span a range of chemical hardness and ligand binding affinity and substituents that allow varying access to the metal, a wide range of volatile analytes are differentiable. Porphyrins also show significant solvochromic effects, so even weakly interacting vapors (e.g., arenes, halocarbons, or ketones) show distinguishable colorimetric effects. Estimates of our sensitivity based on initial experiments and the known growth rates for *E. coli* are ~50 cells/mL after 1 hour of growth and ~10^3 cell/mL for a 10 minute analysis time for a one mL culture volume with 0.25 mL headspace gas volume (based on demonstrated ChemSensing array limit of recognition for acetic acid (~50 ppb) and the production rate of acetic acid by *E. coli* in glucose rich liquid media (1.5 x 10^{-16} moles/bacteria/min at 37°C, pH 7, doubling time 55 min).

Analytical Laboratory Ranking

Preference Set = Analytical Laboratory

ChemSensing Colorimetric Sensor ranked in the bottom third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.

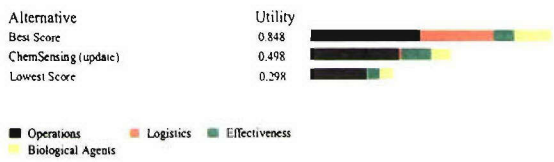
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

ChemSensing Colorimetric Sensor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.

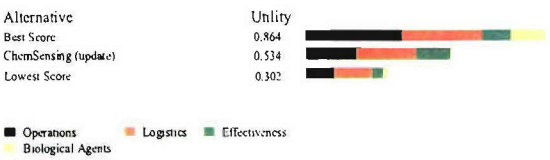
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

ChemSensing Colorimetric Sensor ranked in the middle third of all evaluated products for mobile laboratories and earned 59% of the utility points of the best score.

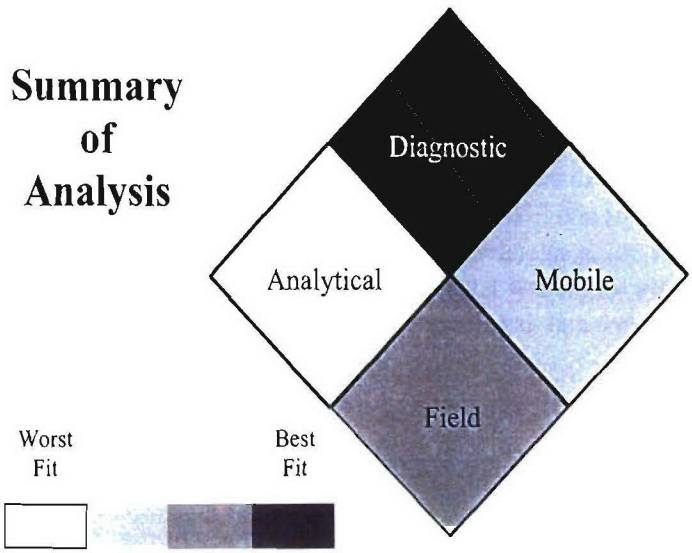
Field Use Ranking



Preference Set = Field Use

ChemSensing Colorimetric Sensor ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.

Summary of Analysis



ChemSensing Colorimetric Sensor Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is expected to be ready for commercialization within one calendar year
- A few devices or systems exist (brass board)

System requirements:
- System or device has a 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 250ul needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- 5-10 min set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- Cleaning involves purging the system with air or nitrogen

Maintenance:
- 2 consumable or expendable needed
- Unknown service required
- Expected life measure is 1-3 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

Cost: $5.00/sample
Estimated $5000.00/system or device

ChemSensing, Inc.
60 Hazelwood Drive
Champaign, IL 61820
www.cemsensing.com

Point of Contact: Joel Dryer
(847) 412-0010
fax. (847) 412-0008
joel@chemsensing.com

Chimera System

by Thermo Hybaid

Description: The Thermo Hybaid Chimera System is a dedicated real time PCR machine capable of performing fast and precise thermal cycling combined with sensitive and accurate fluorescent readings. This combination, along with intuitive software, enables quantitative PCR, end-point analysis and SNP scoring on the one instrument.
The unit is intended for use by both academic and industrial users for the low level detection of both DNA and RNA in real time and its subsequent quantitation.

No Formal Detection Assay Available

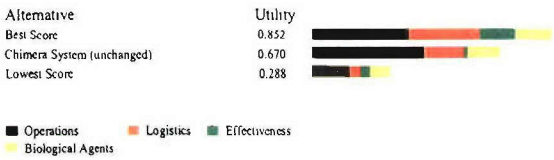
Technology: The Thermo Hybaid Chimera System uses a halogen lamp as excitation source and a PMT as the detection method. By using up to eight filters per reaction it is possible to have an excitation and emission range of 340 to 720nm. The Chimera uses a standard 96 well microplate format (with a gradient block for ease of optimisation) and is totally robot-compatible due to the CD drawer mechanism employed. Detection of 1 copy up to 10^8 copies is possible with a read speed of under 10 sec per filter set.

Analytical Laboratory Ranking

Preference Set = Analytical Laboratory

Chimera System ranked in the top third of all evaluated products for analytical laboratories and earned 74% of the utility points of the best score.

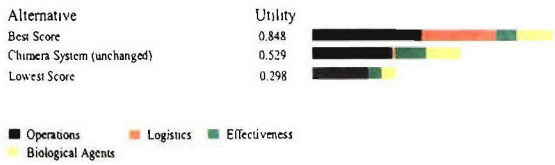
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Chimera System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 79% of the utility of the best score.

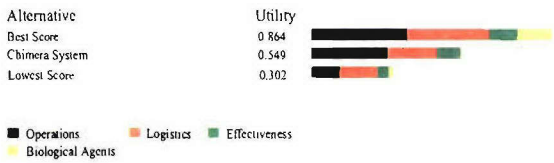
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Chimera System ranked in the middle third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.

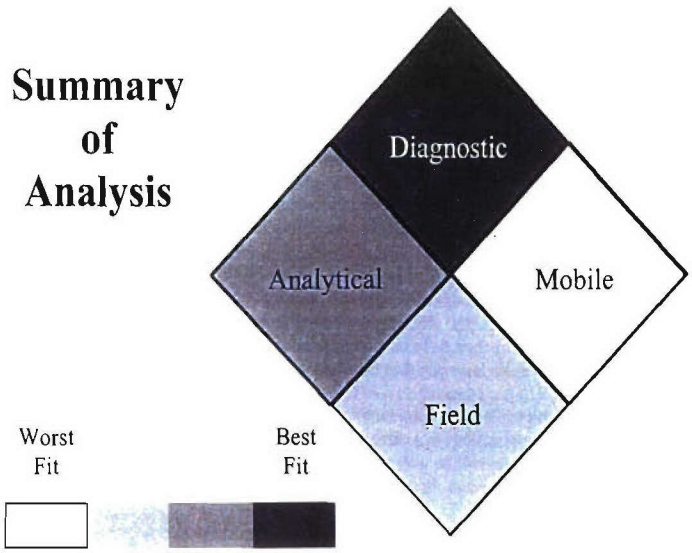
Field Use Ranking



Preference Set = Field Use

Chimera System ranked in the middle third of all evaluated products for field use and earned 64% of the utility points of the best score.

Summary of Analysis



Chimera System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation step
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at room temperature
- Performance of the device or system is unknown at relative humidity

Cost: Dependent on assay/sample
Approx. $50,000.00/system or device

Thermo Hybaid
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fax. +44 1784 248085
miles.schofield@thermo.com

Compact, Quantum Dots Based Biosensor

by The Aerospace Corporation

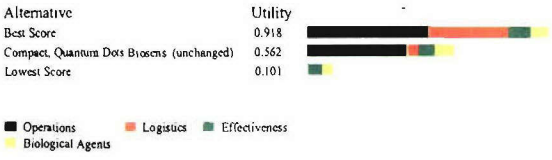
Description: The Aerospace Corporation has been carrying out work toward the development of a miniaturized, immunoassay-based, optical biosensor that has the ability to detect multiple pathogens and/or biological toxins on a single sensing element (e.g., optical fiber or waveguide). This biosensor is based upon the use of a new class of fluorescent labels for antibodies: semiconductor quantum dots. Fluorescent quantum dots are nanocrystals that can readily be tailored to emit different visible and infrared wavelengths of light. An undesirable feature of fluorescent dyes used in the conventional immunoassay sensors is that emission efficiencies of the dyes often degrade with time due to photo bleaching, which could cause the detection signal to drift with time and require frequent calibrations. Quantum dots, on the other hand, are much less sensitive to photobleaching and are thus ideal for field applications that require long-life and reliable service-free operation. Aerospace has demonstrated that, upon being properly bound to antibodies, the quantum dots can be used as optical taggant labels to "color code" different antibodies that are selective for a variety of pathogens and biological toxins. Despite their different color emissions, quantum dots can be all excited by the same UV wavelength. A single diode laser can thus be used to excite a mixture of optical labels producing emission from each quantum dot. The use of quantum dots as antibody taggants will thus allow the use of a very compact device to detect multiple pathogens and biological toxins. The use of quantum dots as optical labels for antibodies will also have applications in a variety of compact biosensors, including array-based immunoassay detectors. Such biosensors will be well-suited for use by the counterproliferation, force protection, and homeland defense communities for detecting the clandestine manufacture, battlefield, or terrorist use of biological weapons.

Technology: In order for quantum dots to be successfully used for biosensor applications, they must first be chemically bound to antibodies in such a way that the quantum dots retain their fluorescence under biologically compatible conditions while the selectivities and affinities of antibodies to their antigens are not degraded. Aerospace has developed methods for synthesizing water-soluble ZnS-capped, CdSe quantum dots as well as methods to chemically bind these quantum dots directly to antibodies. This has enabled the production of a new class of fluorescent-tagged antibody molecules. Aerospace has carried out studies to characterize the antibody-quantum dot complexes spectroscopically, and also studied the stability of these complexes. Aerospace was the first group to report the covalent bonding of an antibody to a quantum dot surface as well as to demonstrate that the quantum dot-labeled antibodies retain specificity to their antigens. Aerospace has developed improved approaches for synthesizing quantum dots of varying sizes and with different emission wavelengths as well as has carried out studies to help understand and control the stability and quantum yield of the water-soluble quantum dots.

No Formal Detection Assay Available

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Compact, Quantum Dots Biosens. (unchanged)	0.562
Lowest Score	0.101

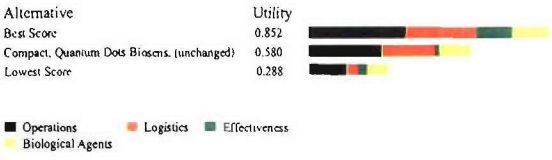


Preference Set = Analytical Laboratory

Compact, Quantum Dots Based Biosensor ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Compact, Quantum Dots Biosens. (unchanged)	0.580
Lowest Score	0.288

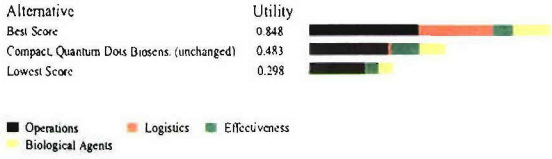


Preference Set = Diagnostic Laboratory

Compact, Quantum Dots Based Biosensor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Compact, Quantum Dots Biosens. (unchanged)	0.483
Lowest Score	0.298

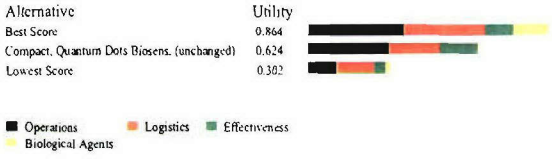


Preference Set = Mobile Laboratory

Compact, Quantum Dots Based Biosensor ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.

Field Use Ranking

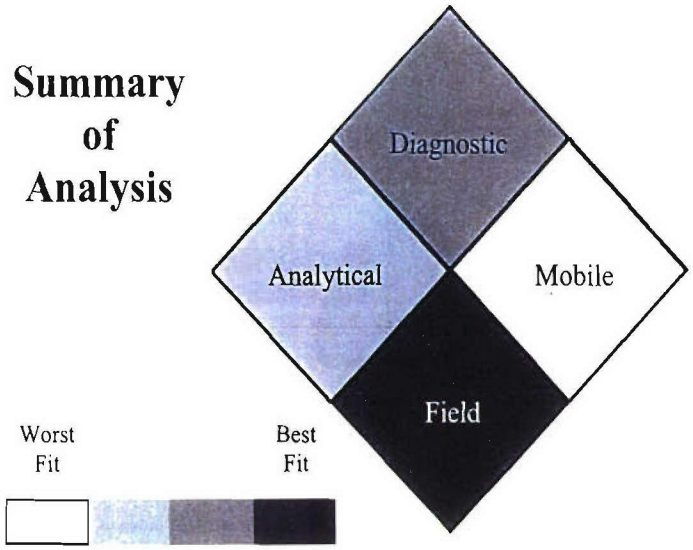
Alternative	Utility
Best Score	0.864
Compact, Quantum Dots Biosens. (unchanged)	0.624
Lowest Score	0.302



Preference Set = Field Use

Compact, Quantum Dots Based Biosensor ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.

Summary of Analysis



Compact, Quantum Dots Based Biosensor Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Only one incomplete device or system exist (bread board)

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device uses batteries
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 384 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- 5-10 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Every 6 months service required
- Expected life is 3-5 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

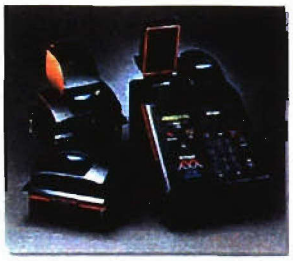
Cost: $Unknown/sample
$Unknown price/system or device

The Aerospace Corporation
P.O. Box 92957
Los Angeles, CA 90009

Point of Contact: Yat Chan
(310) 336-5073
fax. (310) 336-6801
yat.c.chan@aero.org

DNA Engine Thermal Cycler

by MJ Research, Inc.



Able to Detect the following Organisms
Bacillus anthracis (4)
E. coli 0157:H7 (1)
Francisella tularensis (4)
Yersinia pestis (4)
Brucella species (4)
Smallpox virus (4)
Orthopox virus (4)

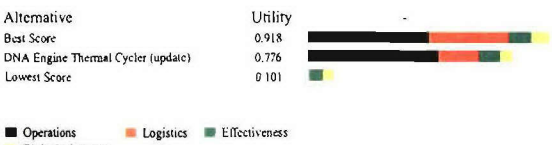
(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Description: With DNA assays that are either PCR-based, or sequence-based -- thermal cyclers are the primary instrument platform required. MJ Research offers a modular design of Peltier-effect thermal cyclers that have become the worldwide "industry standard" instrument since introduction of this third-generation technology in 1994. Today, there are three platforms: the one-block "DNA Engine"; the two-block "DNA Engine Dyad"; and the four-block "DNA Engine Tetrad II". Each of these can be fit with modular "Alpha Unit" interchangeable sample-block/heat-pump assemblies. Standard Alpha Units are available to fit 96x0.2ml tubes (or one 96-well plate); 2x48x0.2ml tubes; 60x0.5ml tubes; 2x30x0.5ml tubes, 384-well plate, 2x eight glass slides (15mmx30mm); or a flat surface for large microarrays or biochips. With the 96-well blocks, all instrument platforms are capable of "gradient" operation, where the block can incubate with a 1°-24°C thermal gradient across its surface, to assist in optimizing protocols. These instruments could readily serve as part of a larger system being designed for the detection/diagnosis/analysis of BW/BT pathogens, where end-product analysis was conducted through gel-electrophoresis or a plate reader or a fluorescence-detection thermal cycler (when using end-point analysis, as with melt curves, 3-4 blocks can "feed" a single fluorescence-detection unit). Within the past year, MJ Research has introduced two major new accessories. The first is the "MotoAlpha", which is a sophisticated motorized heated lid that allows reactions down to one microliter volumes in 96- or 384-well plates. The second is the "Chromo4" Alpha Unit, which is a unique four-color fluorescence-detection unit that allows real-time reactions on these platforms (or end-point analysis of plates through melt-curve analysis).

Technology: The thermal cyclers are microprocessor-controlled precision incubators that operate using the Peltier Effect, which is a fundamental physical phenomenon that pumps heat electronically without any moving parts other than a fan to disperse excess heat. It also allows for a precision and speed of control unrivaled by any other technology with instrumentation working at the scale of laboratory devices. MJ Research was the first company to develop such instrumentation and introduce it commercially (although according to the inventor of PCR and Nobel-laurate, Kary Mullis, the very first "PCR machine" was a Peltier-effect instrument, custom-built circa 1984). MJ introduced its first commercial unit in 1988, and since that time, the technology has virtually supplanted the four other technologies of thermal control used in this molecular-biology application. The DNA Engine line was MJ's third generation of instrument offered. MJ builds its thermal cyclers starting with extremely pure bismuth & tellurium, from which semiconductor crystals are grown in furnaces using a proprietary process. These crystals are then sliced, diced, treated, QC'd and assembled into working "thermoelectric modules," which are then incorporated into increasingly larger assemblies that eventually compose the entire instrument. The result is the best performing, most reliable, and most precise thermoelectric technology in any thermal cycler currently offered. Among the many features the instrument incorporates includes, 1) modularity, where individual "Alpha Unit" sample-block/heat-pump assemblies can be swapped in seconds, 2) speed of ramping that is quite rapid, to allow shorter protocols, 3) precision of control that is NIST-traceable and highly reproducible well-to-well, run-to-run, and instrument-to-instrument, 4) robust and time-proven circuit designs and software, 5) a gradient-block function with the 96-well Alpha that allows a range of temperatures of 1°-24° across the block during any incubation with no loss of NIST-traceable accuracy, 6) a worldwide distribution (and repair) network, such that authorized distributors exist in over forty nations with familiarity with the instrument and an ability to service them, 7) competitive pricing and commercial availability.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
DNA Engine Thermal Cycler (update)	0.776
Lowest Score	0.101

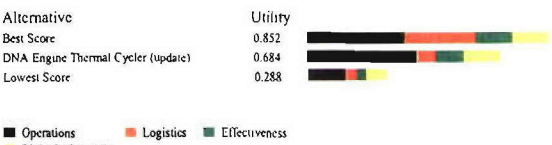


Preference Set = Analytical Laboratory

DNA Engine Thermal Cycler ranked in the top third of all evaluated products for analytical laboratories and earned 85% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
DNA Engine Thermal Cycler (update)	0.684
Lowest Score	0.288



Preference Set = Diagnostic Laboratory

DNA Engine Thermal Cycler ranked in the middle third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
DNA Engine Thermal Cycler (update)	0.602
Lowest Score	0.298

Preference Set = Mobile Laboratory

DNA Engine Thermal Cycler ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.

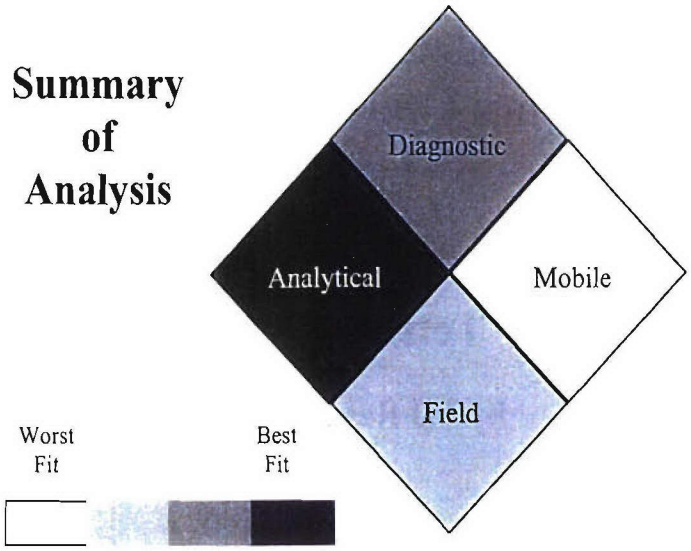
Field Use Ranking

Alternative	Utility
Best Score	0.864
DNA Engine Thermal Cycler	0.637
Lowest Score	0.302

Preference Set = Field Use

DNA Engine Thermal Cycler ranked in the middle third of all evaluated products for field use and earned 74% of the utility points of the best score.

Summary of Analysis



DNA Engine, Dyad & Tetrad Thermal Cyclers Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirements
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- Manual steps required for detection NA

Re-use:
- Device or system is intended for multiple use
- Unknown solution or buffer used
- Unknown components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Needs service less than once a year
- Expected life is 5-10 years
- No daily assurance procedures needed

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Greater than 3 year shelf life

Ease of use/Utility
- Cannot view results "in real time"
- Unknown centrifugation steps
- Unknown shaking or vortexing step
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Unknown additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Unknown components storage
- Performance of the device or system is not influenced by relative humidity

Cost: $unknown/sample
a one-block DNA Engine costs about $7K, a two-block Dyad costs about $13.5K, and a four-block Tetrad II costs about $24K

MJ Research, Inc.
590 Lincoln Street
Waltham, MA 02451
www.mjr.com

Point of Contact: John Hansen
(617) 972-8157 ext. 8157
fax. (617) 923-8080
johnh@mjr.com

Additional Information:
Dyad & Tetrad Thermal Cyclers

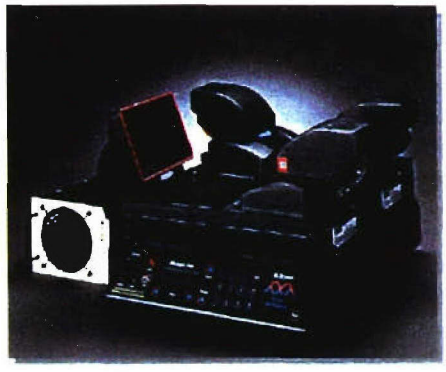
Dyad Cycler

by MJ Research, Inc.

Model PTC-220 Dyad cycler that holds two Alphas and utilizes new control options. The Dyad cycler features a new user interface that offers intuitive, point-and-click programming, real-time graphs of sample, block, and lid temperature, and a color display. Different Alpha units can be operated at the same time, and when two dual-block Alpha units are employed, up to four independent protocols can be simultaneously executed.

Tetrad Cycler

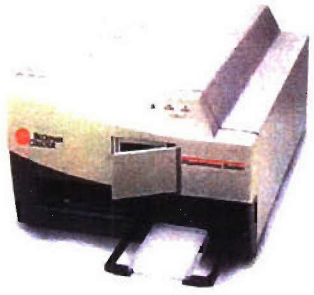
by MJ Research, Inc.



Model PTC-225 Tetrad cycler that holds four Alphas, shown here with "Power Bonnet" heated lids for use in automated applications. The Tetrad fulfills the growing need for high-throughput thermal cycling. The Tetrad uses the same Alpha units as the DNA Engine, delivering the same high level of thermal and operational performance. Any Tetrad block can execute any program in memory, and users can maintain their own password-protected program sets. Using dual blocks, the Tetrad can run up to eight different protocols simultaneously. With four 384-well blocks, it can perform 1536 reactions at once-the highest throughput of any thermal cycler available.

DTX 800 Multimode Detector

by Beckman Coulter

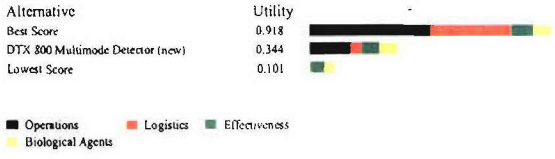


Description: The DTX 800 Multimode detector allows detection via fluorescence, luminescence and absorbance modes. It can operate as standalone instrument or can be integrated seamlessly with automated systems. The DTX 800 is ideal for a broad range of systems biology applications including drug discovery, genomics, proteomics and cell-based research. The DTX 800 unique optics design (patents pending) ensures precise performance and sensitivity across all detection modes. The DTX 800 features fluorescence intensity (top reading), absorbance (visible) and glow luminescence for 96- to 384-well plates. The DTX 800 intuitive software platform provides instrument control and easy protocol development.

No Formal Detection Assay Available

Technology: The DTX 800 Multimode Detector employs high powered LEDs as light sources. A single silicon photodiode and photon counting PMT are used for detection in the 340-650nm range. Filters are used to select specific wavelengths to measure.

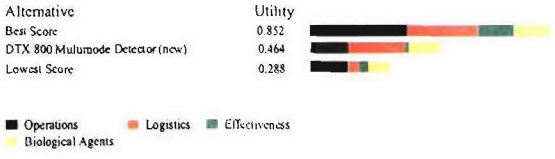
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

DTX 800 ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

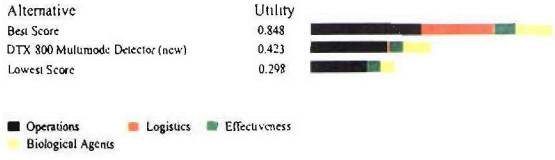
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

DTX 800 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

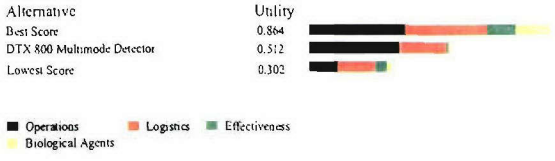
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

DTX 800 ranked in the bottom third of all evaluated products for mobile laboratories and earned 50% of the utility points of the best score.

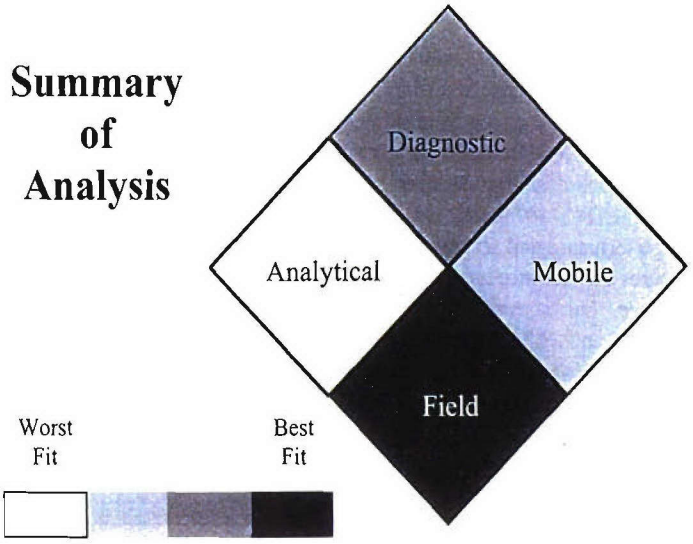
Field Use Ranking



Preference Set = Field Use

DTX 800 ranked in the bottom third of all evaluated products for field use and earned 59% of the utility points of the best score.

Summary of Analysis



DTX 800 Multimode Detector

Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Will be ready for commercialization within one calendar year
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- Number of solutions or buffers used is assay dependent
- 1 component
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Needs service once a year
- Expected system or device life of 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry on luggage suitcase
- Between 5 and 25 kg
- Shelf life measure is not applicable

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting 4 or more targets in a single well
- 2 additional pieces of equipment needed

Signature:
- No sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components storage conditions are not applicable
- Device or system has peak performance at normal relative humidity conditions only

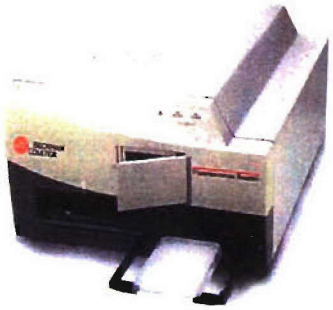
Cost: $unknown/sample
$11,000.00/device

Beckman Coulter
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
www.beckmancoulter.com

Point of Contact:
Matt Maloney, Margaret Kelly
(317) 808-4217, (714) 773-8022
fax.(714) 773-6690
MJMaloney@beckman.com
mmkelly@beckman.com

DTX 880 Multimode Detector

by Beckman Coulter

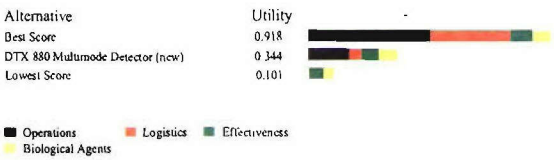


Description: The DTX 880 Multimode detector allows detection via fluorescence, luminescence and absorbance modes. It can operate as standalone instrument or can be integrated seamlessly with automated systems. The DTX 880 is ideal for a broad range of systems biology applications including drug discovery, genomics, proteomics and cell-based research. The DTX 880 unique optics design (patents pending) ensures precise performance and sensitivity across all detection modes. The DTX 880 features fluorescence intensity (top and bottom reading), time-resolved fluorescence, fluorescence polarization, absorbance (UV and visible), glow luminescence and temperature control for 6- to 1536-well plates. The DTX 880 intuitive software platform provides instrument control and easy protocol development.

No Formal Detection Assay Available

Technology: The DTX 880 Multimode Detector employs high powered LEDs and a deuterium lamp for light sources. A single silicon photodiode and photon counting PMT are used for detection in the 230-750nm range. Filters are used to select specific wavelengths to measure.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

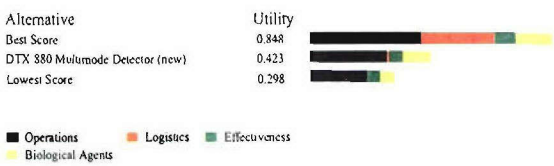
DTX 880 ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

DTX 880 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 54% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

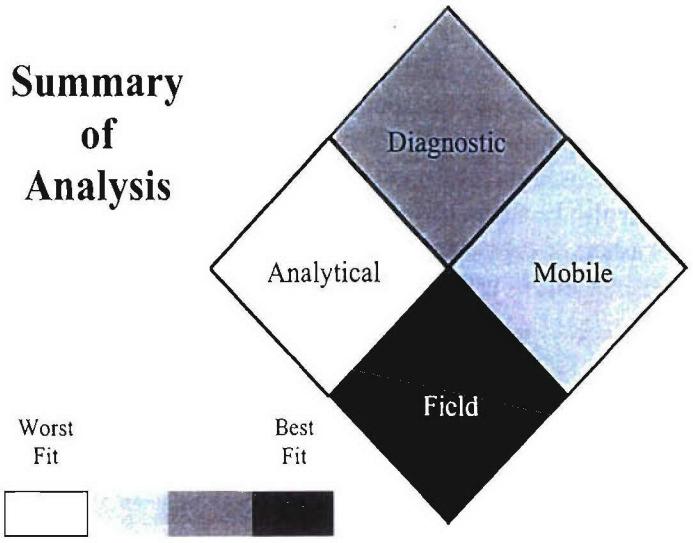
DTX 880 ranked in the bottom third of all evaluated products for mobile laboratories and earned 50% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

DTX 880 ranked in the bottom third of all evaluated products for field use and earned 59% of the utility points of the best score.

Summary of Analysis



DTX 880 Multimode Detector

Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Will be ready for commercialization within one calendar year
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- Number of solutions or buffers used is assay dependent
- 1 component
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Needs service once a year
- Expected system or device life of 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry on luggage suitcase
- Between 5 and 25 kg
- Shelf life measure is not applicable

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting 4 or more targets in a single well
- 2 additional pieces of equipment needed

Signature:
- No sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components storage conditions are not applicable
- Device or system has peak performance at normal relative humidity conditions only

Cost: $unknown/sample
$19,950.00/device

Beckman Coulter
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
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Point of Contact:
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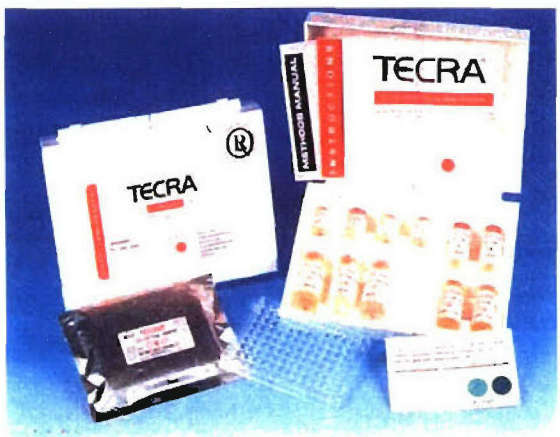
fax.(714) 773-6690
MJMaloney@beckman.com
mmkelly@beckman.com

E. coli 0157 Visual Immunoassay (VIA)

by TECRA International Pty Ltd

Description: A rapid and specific screening test for detection of *E. coli* O157 (including *E. coli* O157:H7 and other enterohaemorrhagic *E. coli* O157 strains) in food and environmental samples. After an overnight enrichment, results can be obtained within 2 hours. The ELISA can be used manually and the results read by eye. However, it can also be semi-automated with the use of microtitre plate readers and washers or fully automated for large scale testing. The kit is available in a 96 and 48 well format.

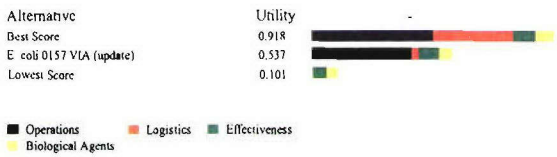


Able to Detect the Following Organism:
E. coli 0157:H7 (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The TECRA E. coli O157 VIA is an Enzyme-linked Immunoassay (ELISA) performed in a sandwich configuration.

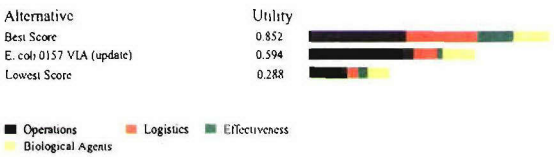
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

E. coli 0157 Visual Immunoassay ranked in the middle third of all evaluated products for analytical laboratories and earned 58% of the utility points of the best score.

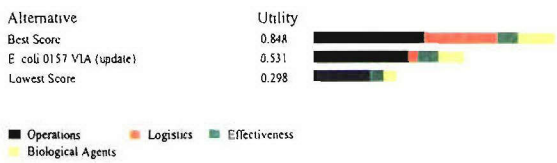
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

E. coli 0157 Visual Immunoassay ranked in the middle third of all evaluated products for diagnostic laboratories and earned 70% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

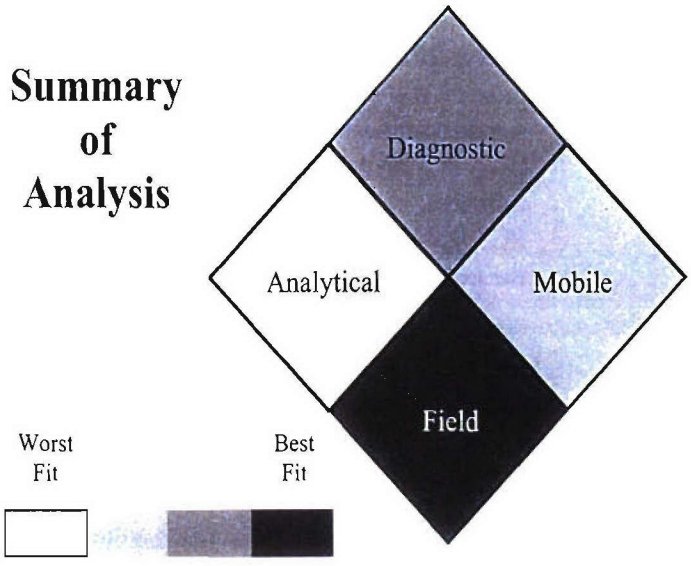
E. coli 0157 Visual Immunoassay ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

E. coli 0157 Visual Immunoassay ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

Summary of Analysis



E. coli 0157 Visual Immunoassay (VIA) Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is designed for single use
- More than 4 solutions or buffers used
- 5 or more components
- NA cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life NA
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $7.00/sample
$306.00 for 48 wells, $557.00 for 96 wells/system or device

TECRA International Pty Ltd
13 Rodborough Rd.
Frenchs Forest, NSW 2086 Australia
www.tecra.net

Point of Contact: Nick Vale
+61 2 8977011
fax. +61 2 9453 3422
nick.vale@tecra.net

Eppendorf Mastercycler

by Eppendorf

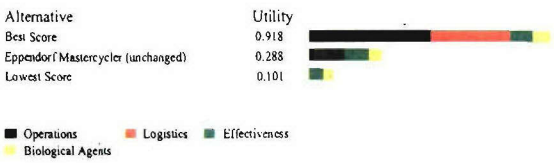
Steady Slope

Description: The Eppendorf Mastercycler gradient thermal cycler is a relatively small-sized instrument designed to quickly multiply DNA and RNA by rapidly heating and cooling samples. Samples should be placed in tubes or PCR plates along with a Mastermix and run on the instrument for 30 to 40 cycles.

No Formal Detection Assay Available

Technology: The Eppendorf Mastercycler gradient thermal cycler uses Peltier heating and cooling technology. The instrument is designed to perform temperature and time holding combinations from 4 degrees celcius to 99 degrees celcius and from 1 second to 99 hours 99 minutes and 99 seconds. The instrument is also equipped with Triple Circuit Technology (TCT) which allows for an almost linear 1 to 20 degree celeius gradient function. This function can be used to minimize assay optimization. Mastercyclers come equipped with a removable Personal Card on which the user can store up to 10 protocols. It is relatively small and lightweight and does not take up much bench space.

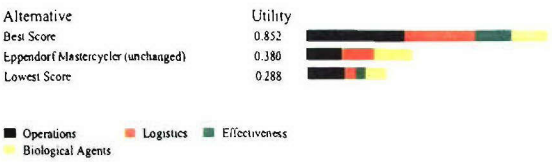
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Eppendorf Mastercycler ranked in the bottom third of all evaluated products for analytical laboratories and earned 31% of the utility points of the best score.

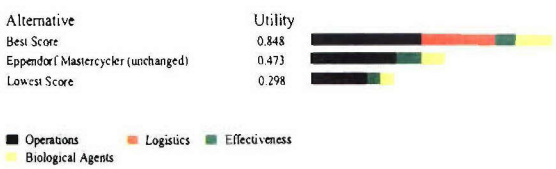
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Eppendorf Mastercycler ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 45% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

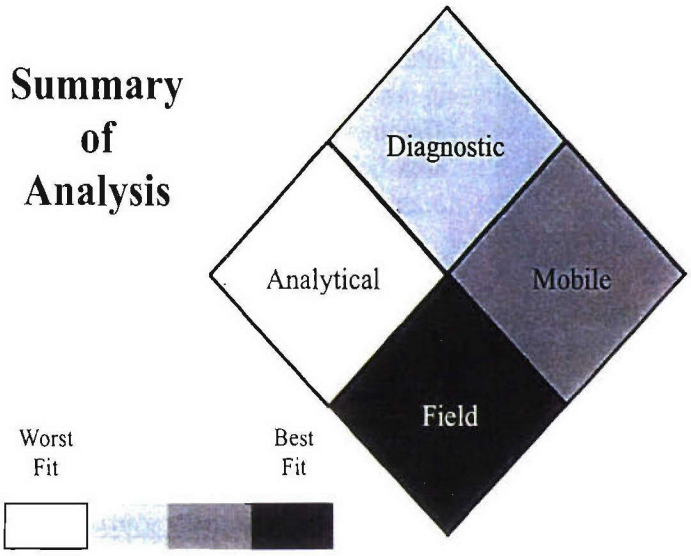
Eppendorf Mastercycler ranked in the bottom third of all evaluated products for mobile laboratories and earned 56% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

Eppendorf Mastercycler ranked in the bottom third of all evaluated products for field use and earned 60% of the utility points of the best score.

Summary of Analysis



Eppendorf Mastercycler Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Once a year service required
- Expected life is 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be frozen
- Performance of the device or system is unknown in humidity

Cost: $1.50/sample
$7,885.00 GSA price/system or device

Brinkmann
One Cantiague Rd.
Westbury, NY 11590
www.brinkmann.com

Point of Contact: Stefanie Ellis
(516) 515-2337
fax. (516) 334-7521
sellis@brinkmann.com

Guardian Reader

by Tetracore Inc. and
Alexeter Technologies

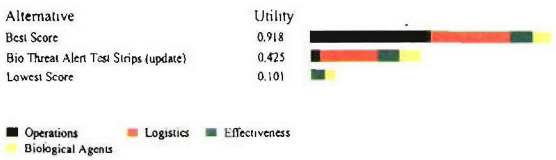
Description: The *Bio Threat Alert* is intended for biological agent screening in environmental samples. The *Bio Threat Alert Test Strip* is designed for both field and laboratory use but is ***not intended for use on clinical samples.***

Technology: The *Guardian Reader* is designed to accept and analyze only *Bio Threat Alert Test Strips* and will automatically identify the type of *Bio Threat Alert Test Strip* (i.e., anthrax, botulinum, etc.) prior to analysis. The Operator is automatically navigated through the test procedure via LCD displayed instructions. The *Guardian Reader* provides an objective evaluation of the test result relative to the assigned *Bio Threat Alert* Test Strip batch threshold, displays the result, prints a report and records the full test result in non-volatile memory. The operator has the option in selecting either MANUAL or AUTO reading modes. MANUAL mode is selected for immediate analysis of *Bio Threat Alert* Test Strips that have already completed the test incubation outside the Reader. The AUTO mode is selected when the Operator desires the Reader to precisely time the *Bio Threat Alert* Test Strip incubation before analysis.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (3)
Francisella tularensis (3)
Yersinia pestis (3)
Brucella species (3)
Orthopox virus (3)
Botulinum toxins A, B (3)
SEB (3)
Ricin (3)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

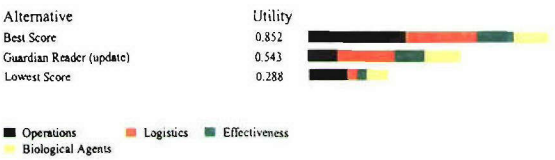
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Bio Threat Alert Test Strips ranked in the bottom third of all evaluated products for analytical laboratories an earned 46% of the utility points of the best score.

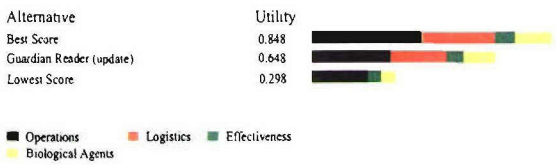
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Bio Threat Alert Test Strips ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 64% of the utility points of the best score.

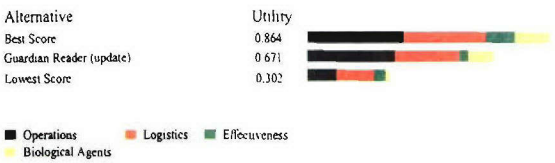
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Bio Threat Alert Test Strips ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.

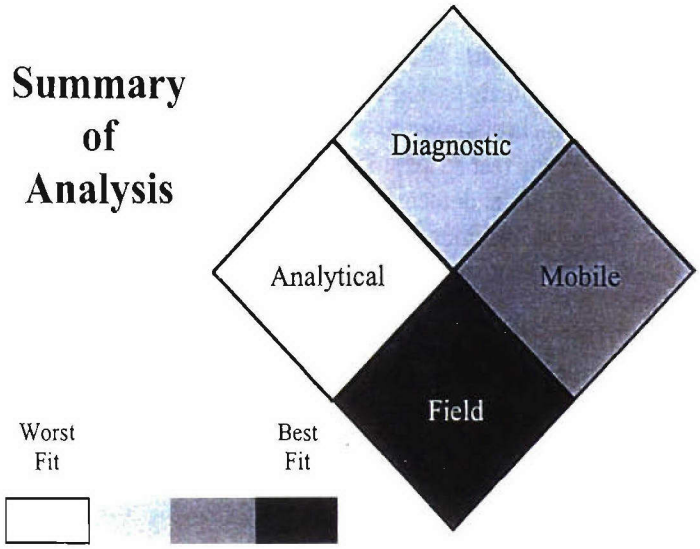
Field Use Ranking



Preference Set = Field Use

Bio Threat Alert Test Strips ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.

Summary of Analysis



Guardian Reader Evaluation Criteria Provided by Vendor

Sensitivity:
- Greater than 100,000 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Re-use:
- Device or system intended for multiple use
- 0-1 solution or buffer used
- 5 components
- No cleaning required

Maintenance:
- 4 consumables or expendables needed
- No service required
- Expected life is 5-10 years
- No daily quality assurance procedures necessary

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Peak performance at normal relative humidity conditions only

Cost: $4,500.00/reader

Tetracore, Inc.
11 Firstfield Road
Gaithersburg, MD 20878
www.tetracore.com

Alexeter Technologies
830 Seton Court, Suite 6
Wheeling, IL 60090
www.alexeter.com

Points of Contact:

Tetracore
Tom O'Brien
(301) 258-7553
fax. (301) 258-9740
tobrien@tetracore.com

Alexeter
Jim Whelan
(847) 419-1507
fax. (847) 419-1648
jwhelan@alexeter.com

Handheld Fluorescence Strip Reader

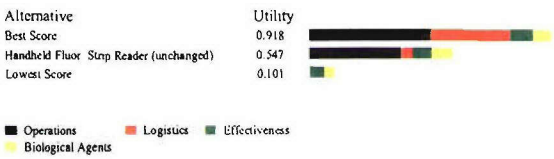
by OmniSite BioDiagnostics, Inc.

Description: The Handheld Fluorescence Strip Reader detects biological warfare agents on immunochromatographic test strips (similar to pregnancy test strips). In practice, 3 – 4 different agents can be detected on a single strip at low levels. The unit also contains a wireless data link to transfer detection data to a central location such as a website.

No Formal Detection Assay Available

Technology: A scanning epifluorescent head scans across the immunochromatographic test strip antibody capture lines and reads the fluorescence intensity along each capture line. These intensities are automatically compared with the intensity of control lines to determine if a biowarfare agent is present or not.

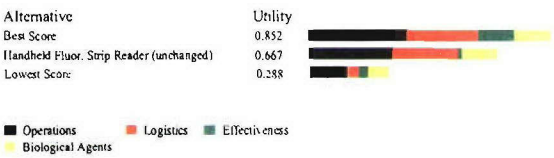
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Handheld Fluorescence Strip Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

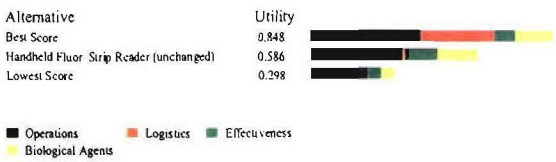
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Handheld Fluorescence Strip Reader ranked in the middle third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.

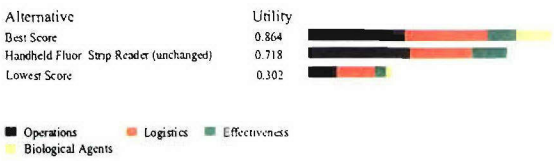
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Handheld Fluorescence Strip Reader ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.

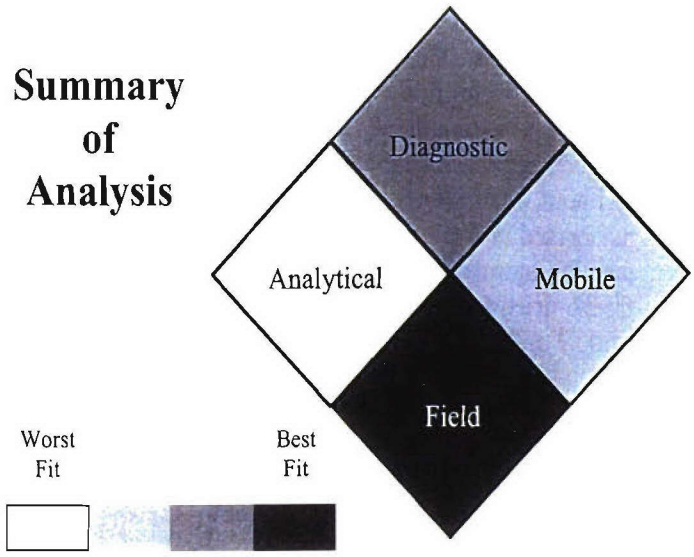
Field Use Ranking



Preference Set = Field Use

Handheld Fluorescence Strip Reader ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

Summary of Analysis



Handheld Fluorescence Strip Reader Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- A few devices or system exist (brass board)

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- No service required
- Expected life is greater than10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life greater than 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

Cost: Approx. $2.00/sample
Approx. $3,000.00/system or device

OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact: John G. Bruno
(512) 479-7732 ext. 2202
fax. (512) 494-0756
bruno@spec.com

Handheld Fluorescence Polarization (FP) Reader

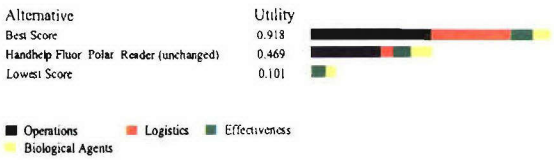
by OmniSite BioDiagnostics, Inc.

Description: This instrument is a miniaturized (16 x 16 x 9 cm) fluorescence polarization (FP) device (excluding the laptop controller and data logger), capable of rapid one-step immunoassays (without wash steps). Although assays are currently performed in 2 mL of fluid in a cuvette, OmniSite is developing microfluidic cartridges that will contain freeze-dried reagents that can be rehydrated by the sample and assessed within minutes.

No Formal Detection Assay Available

Technology: FP is popular technique in the research and clinical diagnostic arenas, because it allows "homogenous" one-step assays (without wash steps) that are especially well suited to small molecule targets. However, FP measures rotational or tumbling speed of fluorophores before and after a molecular complex (e.g., antibody-antigen or aptamer-target complex) and is adaptable to a variety of targets such as proteins and even whole bacteria or other microbes. In the clinical diagnostic world, Abbott Laboratories has dominated with its industry standard table top FP device called the "TDx" for therapeutic drug monitoring and assessing drugs of abuse in serum samples. The OmniSite FP handheld instrument has demonstrated comparable sensitivity to the much larger and heavier table top Abbott TDx unit.

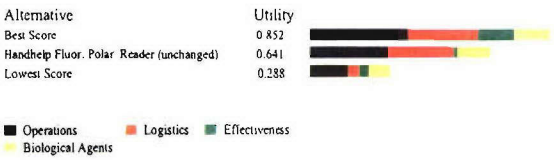
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Handheld Fluorescence Polarization Reader ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

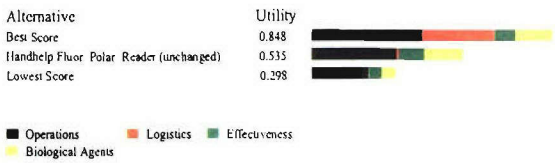
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Handheld Fluorescence Polarization Reader ranked in the middle third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.

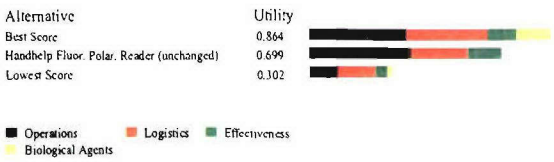
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Handheld Fluorescence Polarization Reader ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

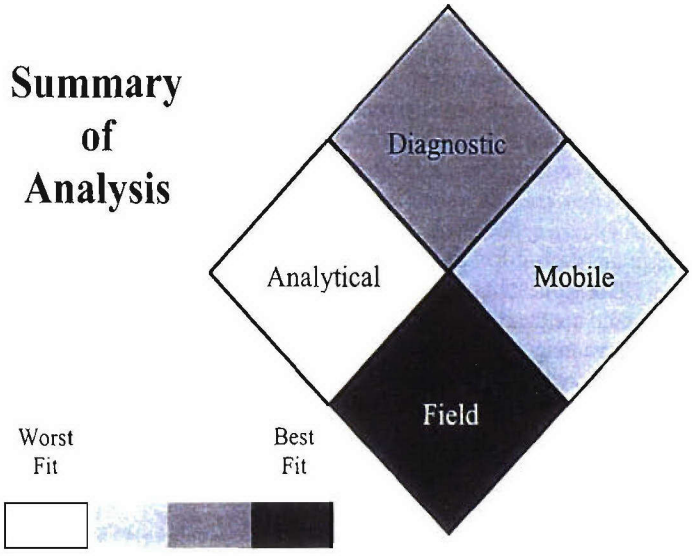
Field Use Ranking



Preference Set = Field Use

Handheld Fluorescence Polarization Reader ranked in the middle third of all evaluated products for field use and earned 81% of the utility points of the best score.

Summary of Analysis



Handheld Fluorescence Polarization (FP) Reader Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- A few devices or system exist (brass board)

System requirements:
- System or device has 110V or battery requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- Expected life is greater than10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- A single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

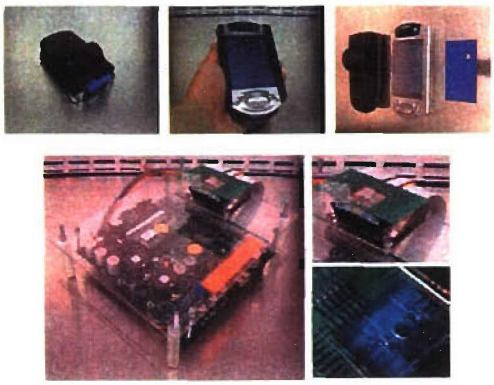
Cost: $0.10/sample
$3,000.00/system or device

OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact: John G. Bruno
(512) 479-7732 ext. 2202
fax. (512) 494-0756
bruno@spec.com

HandyLab-EIMB

by HandyLab Inc.



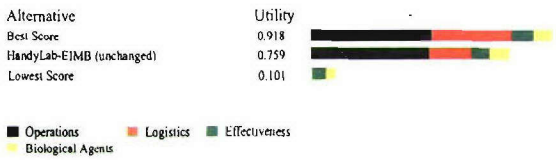
Description: The components of the HandyLab-EIMB system have undergone extensive development and are being integrated into a portable, low-cost, rapid, user-friendly DNA analysis system for commercial medical applications. We can easily adapt our state-of-the-art technology to custom DOD applications. Military personnel could use the handheld device, with minimal training and expense, to perform multiplexed PCR testing for the presence of pathogens and have definitive results within 30 minutes or less.

Able to Detect the Following Organisms/Toxin:
Bacillus anthracis (1)
Francisella tularensis (1)
Yersinia pestis (1)
Brucella species (1)
E. coli 0157:H7 (1)
Marburg virus (1)
Orthopox virus (1)
VEE virus (1)
Latrotoxin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The HandyLab device is a microfluidic-based sensing system that offers several key advantages:
All wet chemistry, optical scans, and DNA assays performed on HandyLab's chips are proven analysis techniques that represent the gold standards in genetic BW identification (PCR). The HandyLab™ solution provides an almost "hands-free" technology, other than the loading and unloading of the cartridge, reducing the risk of human error. The sensitivity equals or exceeds that of existing PCR technology. The technology utilizes nano-volume samples and reagent plugs to perform analyses in less than 30 minutes. All operations are performed on a single chip using a proprietary design with minimal unused volume and reduced transport distances. Tests for different pathogens will be performed in parallel on EIMB's chip array.
HandyLab chips have been designed to operate with independent series and parallel analysis paths for multi-step biochemical analysis. Accordingly, each lab-on-a-chip system can be custom designed to perform only those biochemical analysis functions essential to assess specified samples. The technology allows the user to carry what is currently "bench-top" equipment in the palm of their hand. Every test will be accompanied by on-board positive and negative controls to ensure the accuracy of a result. The chips will be produced using inexpensive microfabrication and injection molding techniques.
HandyLab chips have been designed to operate with independent series and parallel analysis paths for multi-step biochemical analysis. Accordingly, each lab-on-a-chip system can be custom designed to perform only those biochemical analysis functions essential to assess specified samples.

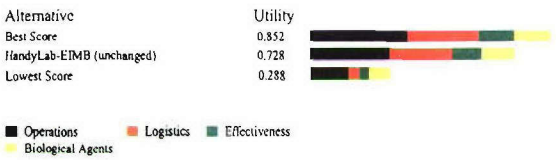
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

HandyLab-EIMB ranked in the top third of all evaluated products for analytical laboratories and earned 83% of the utility points of the best score.

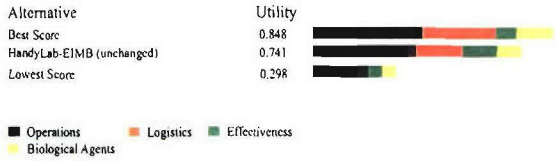
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

HandyLab-EIMB ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

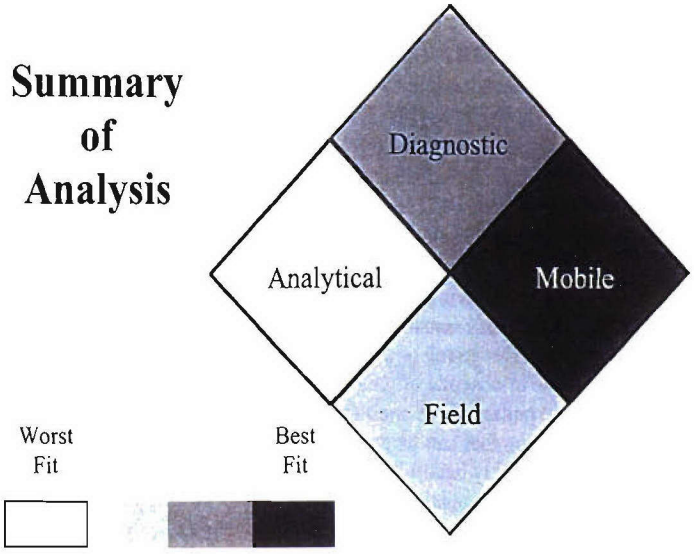
HandyLab-EIMB ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

HandyLab-EIMB ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.

Summary of Analysis



HandyLab-EIMB Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 2 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Unknown service required
- NA expected life
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life greater than 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

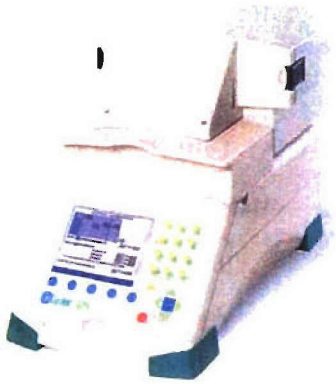
Cost: $1.00-10.00/sample test cartridge
$100.00-200.00 PDA reader/system or device

HandyLab Inc.
3985 Research Park Dr.
Ann Arbor, MI 48108
www.handylab.com

Point of Contact: Dr. Charles Daitch
(734) 663-4719 ext. 240
fax. (734) 663-7437
cdaitch@handylab.com

iCycler iQ

by Bio-Rad Laboratories



Description: The iCycler iQ Real-Time Detection System is, in essence a system that allows for the monitoring of up to four distinct fluorophores (used as markers for individual polymerase chain reactions – PCRs) from a sample at one time. PCR allows a researcher to study different pieces of DNA or genes from specific organisms. The iCycler iQ allows a researcher to look for the presence of up to four targets in each sample being tested. And because this test is based on the polymerase chain reaction – a way of amplifying the amount of starting material a researcher has - it is a very sensitive and quantitative method. A sample, e.g. a piece of tissue or a soil sample, can be tested for the presence or absence of up to four different pieces of DNA from specific pathogens at one time, increasing the amount of information that can be gathered from each sample. Real-time PCR is quickly becoming the accepted method for accurate qualitative and quantitative measurements of viral load, pathogen detection and gene expression.

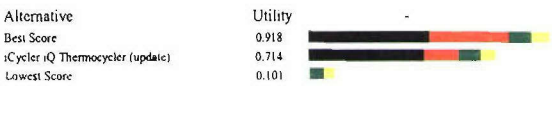
Technology: The iCycler iQ uses a halogen lamp for broad excitation, then employs both excitation and emission narrow band pass filters for discrimination between the many fluorescent reporter molecules that can be employed in real-time PCR. The system uses a proprietary intensifier technology (like used in the U.S. military's night vision technology) and a 10-bit CCD. Our illumination and detection strategy allows for the simultaneous capture of an image of a 96-well PCR plate – in this way up to 96 samples, can be read at one time. The thermal cycler that the detection system is mounted on is a Peltier-based cycler, with the best all-around market specifications for thermal cyclers (gradient capable, heating 3.3 C/sec; cooling 2.0 C/sec). A full description of the technical specifications for the detector and the thermal cycler can be found at: www.bio-rad.com/amplification.

Able to Detect the Following Organisms:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (4)
Brucella species (4)
Orthopox virus (4)
Smallpox virus (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
iCycler iQ Thermocycler (update)	0.714
Lowest Score	0.101

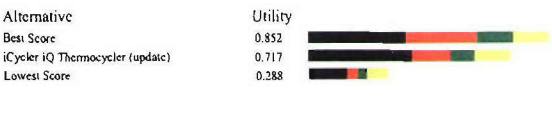


Preference Set = Analytical Laboratory

iCycler iQ ranked in the top third of all evaluated products for analytical laboratories and earned 78% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
iCycler iQ Thermocycler (update)	0.717
Lowest Score	0.288

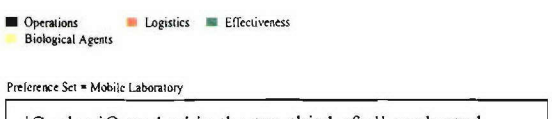


Preference Set = Diagnostic Laboratory

iCycler iQ ranked in the top third of all evaluated products for diagnostic laboratories and earned 84% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
iCycler iQ Thermocycler (update)	0.636
Lowest Score	0.298

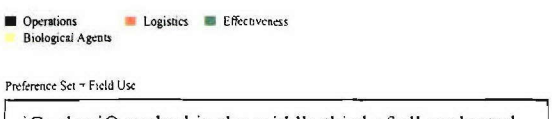


Preference Set = Mobile Laboratory

iCycler iQ ranked in the top third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

Field Use Ranking

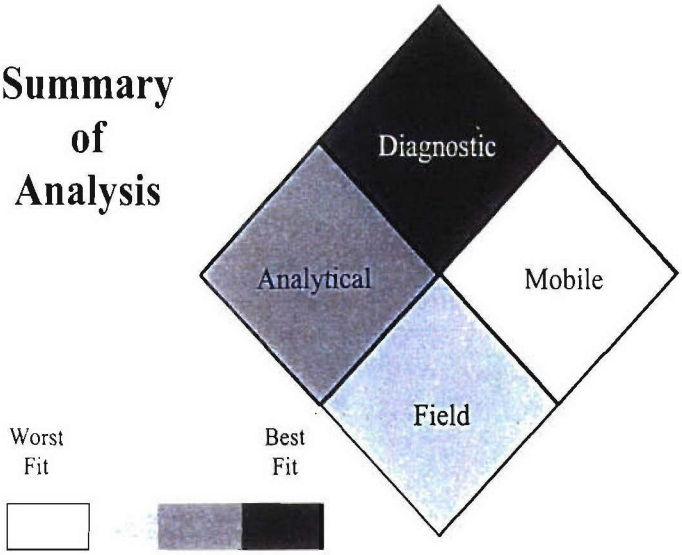
Alternative	Utility
Best Score	0.864
iCycler iQ Thermocycler (update)	0.656
Lowest Score	0.302



Preference Set = Field Use

iCycler iQ ranked in the middle third of all evaluated products for field use and earned 76% of the utility points of the best score.

Summary of Analysis



iCycler iQ Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation step
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 40 and 50 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 10-20 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 4 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life greater than 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C and room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $0.50-2.00/sample
$40,000.00/system or device

Bio-Rad Laboratories
2000 Alfred Nobel Drive
Hercules, CA 94547
www.bio-rad.com/iCycler

Point of Contact: Hilary Srere
(510) 741-6940
fax. (510) 741-5811
hilary_srere@bio-rad.com

Immulite 2000

by DPC

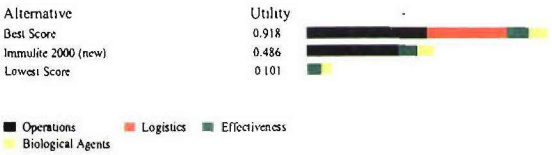
Description: The **IMMULITE 2000** system utilizes specific antibody-coated polystyrene beads as a solid phase. A bead is dispensed into a specially designed Reaction Tube, which serves as the vessel for the incubation, wash and signal development process.

No Formal Detection Assay Available

Technology: After the sample is incubated with alkaline phosphatase-labeled reagent, the reaction mixture is separated from the bead by spinning the Reaction Tube at a high-speed along its vertical axis. The fluid is transferred to a coaxial sump chamber, which is integral to the Bead/Tube Wash Station. Four discrete washes occur within seconds, allowing the Reaction Tubes to be processed sequentially, with uniform timing. The bead is left with no residual unbound label. The bound label is then quantified using the dioxetane substrate to produce light. Light is emitted when the chemiluminescent substrate reacts with the alkaline phosphatase label bound to the bead. The amount of light emitted is proportional to the amount of analyte originally present in the sample. The light emission is detected by the photomultiplier tube (PMT) and results are calculated for each sample. The instrument temperature is 37°C (+- 1 °C). Detection limit of 10-21

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Immulite 2000 (new)	0.486
Lowest Score	0.101

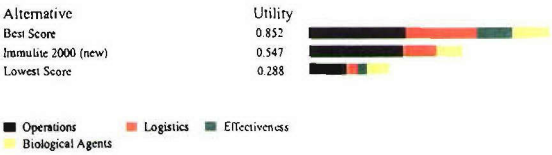


Preference Set = Analytical Laboratory

Immulite 2000 ranked in the bottom third of all evaluated products for analytical laboratories and earned 53% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Immulite 2000 (new)	0.547
Lowest Score	0.288

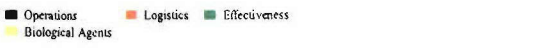


Preference Set = Diagnostic Laboratory

Immulite 2000 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 64% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Immulite 2000 (new)	0.335
Lowest Score	0.298

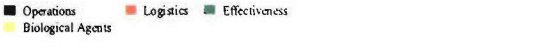


Preference Set = Mobile Laboratory

Immulite 2000 ranked in the bottom third of all evaluated products for mobile laboratories and earned 40% of the utility points of the best score.

Field Use Ranking

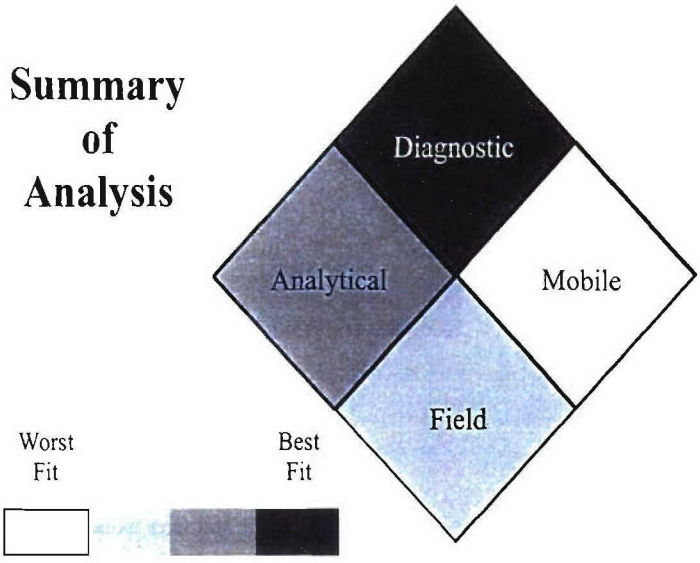
Alternative	Utility
Best Score	0.864
Immulite 2000	0.437
Lowest Score	0.302



Preference Set = Field Use

Immulite 2000 ranked in the bottom third of all evaluated products for field use and earned 51% of the utility points of the best score.

Summary of Analysis



Immulite 2000 System
Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has greater than 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 min
- 384 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- More than a day of training
- Greater than 20 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 4 solution or buffer used
- 2 components
- 5 minutes/day cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Needs service every 6 months
- Expected life measure of 5-10 years
- Greater than 20 minutes required for daily quality assurance procedures

Transportation:
- Larger than the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- A single centrifugation steps
- No shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Device or system has peak performance at normal relative humidity conditions only

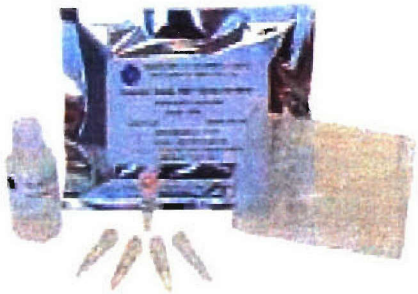
Cost: $2-13/sample
$124,500/device or system

DPC
5700 W 96th Street
Los Angeles, CA 90045-5597
www.dpcweb.com

Point of Contact: Mark Smith
310-642-5180 x7031
310-642-0192 fax
msmith@dpconline.com

Invader Assay

by The Third Wave (TWT)

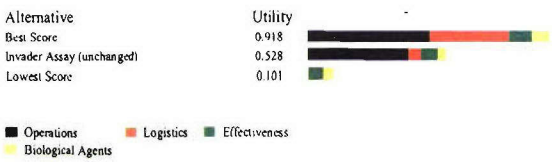


Description: The Invader Assay is an easy to use molecular analysis test. It can detect specific DNA or RNA sequences without the need for Polymerase Chain Reaction (PCR).

No Formal Detection Assay Available

Technology: The Third Wave™ Invader® DNA Assays use Cleavase® enzymes to recognize and cleave specific structures formed by the addition of two oligonucleotides to a nucleic acid target. In the Invader® DNA Assay, two oligonucleotides (a discriminatory Primary Probe and an Invader® Oligo) hybridize in tandem to the target DNA to form an overlapping structure. The 5'-end of the Primary Probe includes a 5'-flap that does not hybridize to the target DNA (Figure 1). The 3'-nucleotide of the bound Invader® Oligo overlaps the Primary Probe, but need not hybridize to the target DNA. The Cleavase® enzyme recognizes this overlapping structure and cleaves off the unpaired 5'-flap of the Primary Probe, releasing it as a target-specific product. The Primary Probe is designed to have a melting temperature close to the reaction temperature. Thus, under the assay conditions, the Primary Probe cycles on the target DNA isothermally. This allows for multiple rounds of Primary Probe cleavage for each target DNA, and amplification of the number of released 5'-flaps. In the secondary reaction, each released 5'-flap can serve as an Invader® Oligo on a fluorescence resonance energy transfer (FRET™) cassette to create another overlapping structure that is recognized and cleaved by the Cleavase® enzyme (Figure 1). When the FRET™ cassette is cleaved, the fluorophore (F) and quencher (Q) on the FRET™ cassette are separated, generating detectable fluorescence signal. Similar to the initial reaction, the released 5'-flap and the FRET™ cassette cycle, resulting in amplified fluorescence signal. The initial and secondary reactions run concurrently in the same well.The biplex format of the Invader® DNA Assay enables simultaneous detection of two DNA sequences in a single well. Most often, this involves detection of two variants of a particular polymorphism. The biplex format uses two different discriminatory Primary Probes, each with a unique 5'-flap, and two different FRET™ cassettes, each with a spectrally distinct fluorophore. By design, the released 5'-flaps will bind only to their respective FRET™ cassettes to generate a target-specific signal.

Analytical Laboratory Ranking



Preference Set – Analytical Laboratory

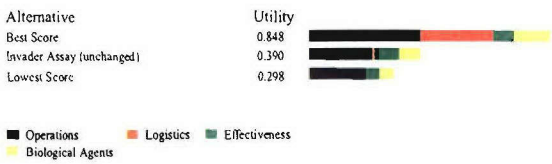
Invader Assay ranked in the middle third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set – Diagnostic Laboratory

Invader Assay ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 57% of the utility points of the best score.

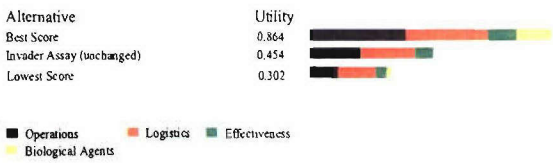
Mobile Laboratory Ranking



Preference Set – Mobile Laboratory

Invader Assay ranked in the bottom third of all evaluated products for mobile laboratories and earned 46% of the utility points of the best score.

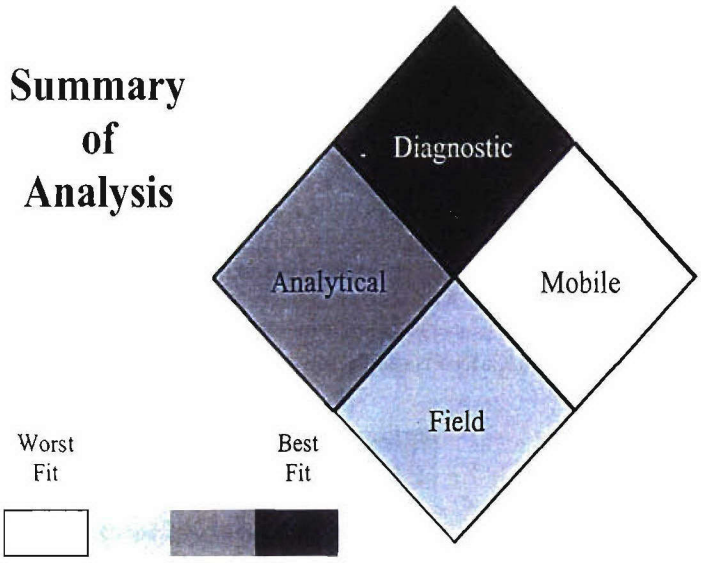
Field Use Ranking



Preference Set – Field Use

Invader Assay ranked in the bottom third of all evaluated products for field use and earned 53% of the utility points of the best score.

Summary of Analysis



Invader Assay Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- More than a day of training
- Greater than 20 minutes required for set-up
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 25 and 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System is never able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:
- Sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be frozen
- Unknown performance of the device or system in humidity

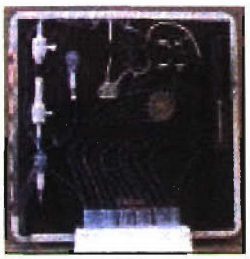
Cost: $0.50/sample
$42,761.00 GSA price/system or device

Third Wave Tech.
502 South Rosa Rd.
Madison, Wisconsin 53719
www.twt.com

Point of Contact: Bruce Neri
(608) 663-7030
bneri@twt.com

KinExA 3000

by Sapidyne Instruments Inc.



Description: The KinExA (Kinetic Exclusion Assay) 3000 is designed to measure molecular interaction in solution phase. The KinExA is distinct from both competition and sandwich assays, in that it measures directly from a solution the amount of free receptor or antibody. The KinExA 3000 was specifically designed to measure the interaction, equilibrium binding and kinetics, of biomolecule binding partners (most commonly antibody and antigen) without the need to modify either partner. The KinExA has been used for the characterization of antibody/antigen pairs numerous times (See attached reference list). The KinExA 3000 has also been used to measure environmental estrogens, organophosphates, and as a biosensor for heavy metal ions in solution. Operation of the KinExA is simple, routine and easily handled by a semi-skilled operator.

No Formal Detection Assay Available

Technology: The KinExA is a general purpose flow fluorimeter capable of detecting low concentrations of free antibody or receptor in solution phase. The detection technology is based on capture of the free antibody or receptor on an immobilized ligand column. The immobilized capture reagent is held in a capillary flow cell embedded in a lens and backed by a reflective surface. Excitation and emission collection is via a conventional epi-illumination filter design. As the sample is passed over the capture reagent, free receptor or antibody is captured and subsequently detected with a fluorescently labeled secondary antibody. When functioning to measure equilibrium constants, the equilibrated sample is rapidly passed over the column, limiting the contact time between sample and immobilized ligand. This insures that the sample equilibrium is not disrupted during measurements. Larger volumes can be accommodated allowing concentration of proteins in dilute samples. This enables the KinExA to have sensitivities in the low pico-molar range for some antibodies. The ability to handle large volumes (more than 5 mL) could conceivably allow the user to measure extremely dilute samples and still obtain reliable measurements. We routinely measure samples in the low-picomolar concentration range with larger volumes. This could apply to analysis of most any molecule if the proper bio-detection protein could be engineered.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
KinExA 3000 (unchanged)	0.192
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

KinExA 3000 ranked in the bottom third of all evaluated products for analytical laboratories and earned 21% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
KinExA 3000 (unchanged)	0.433
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

KinExA 3000 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 51% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
KinExA 3000 (unchanged)	0.315
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

KinExA 3000 ranked in the bottom third of all evaluated products for mobile laboratories and earned 37% of the utility points of the best score.

Field Use Ranking

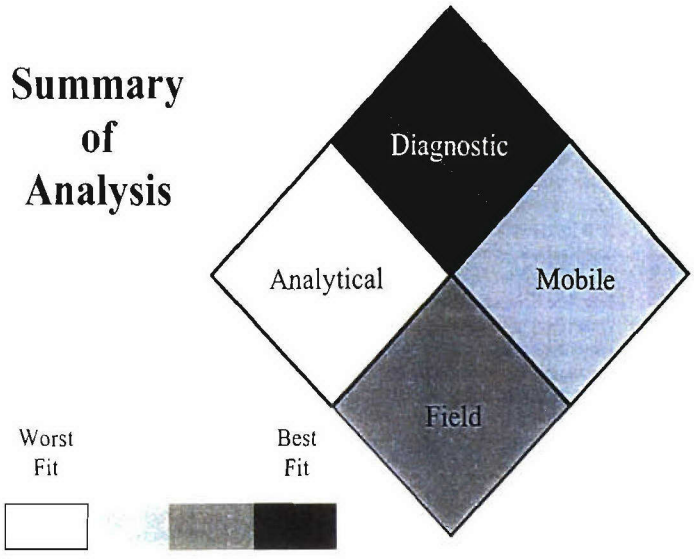
Alternative	Utility
Best Score	0.864
KinExA 3000 (unchanged)	0.422
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

KinExA 3000 ranked in the bottom third of all evaluated products for field use and earned 49% of the utility points of the best score.

Summary of Analysis



KinExA 3000 Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- NA
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 5 or more components
- Requires a buffer rinse between similar samples on the same line, weekly rinse and monthly rinse

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Maintenance:
- 5 or more consumables or expendables needed
- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Training/Speed/Manpower:
- A day of training
- Greater than 20 minutes required for set-up
- 0-2 manual steps required for detection

Transportation:
- Approximately the size of a home dishwasher
- Between 25 and 50 kg
- Shelf life unknown

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $unknown/sample
$78,000.00/system or device

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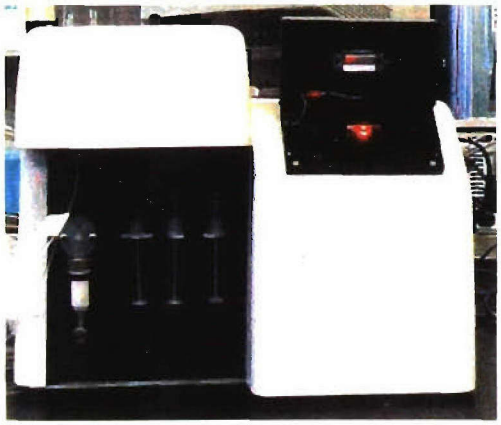
steve@sapidyne.com rmark@sapidyne.com

KinExA Bench Top

by Sapidyne Instruments

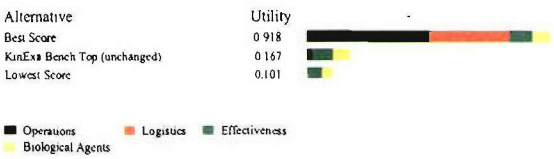


Description: The KinExA (Kinetic Exclusion Assay) technology is a superior method of measuring biological binding interactions. The KinExA is distinct from both competition and sandwich assays, in that it measures directly the free portion of antibody in a sample, while ignoring the complexed portion. This is done without perturbing the mixture, as competition assays do, and will work with small antigens, unlike sandwich assays. The KinExA benchtop instrument was specifically designed to measure the concentration of a ligand in a liquid sample. The focus of the benchtop instrument is to automate the assay steps, thus reducing the skill level needed to perform the assay.
The KinExA technology (using the KinExA 3000 instrument) has been used for the characterization of antibody/antigen pairs numerous times (See attached reference list). The KinExA 3000 has also been used to prove the principle of using KinExA technology to measure environmental estrogens, organophosphates, and as a biosensor for heavy metal ions in solution. While the specific assays are not yet developed for the benchtop instrument, proof of principle was completed using the larger and more expensive laboratory version of the KinExA instrument.

No Formal Detection Assay Available

Technology: The KinExA is a method capable of rapidly detecting low concentrations of free antibody or receptor in solution phase. The detection technology is based on capture of the free antibody or receptor on an immobilized ligand column. The immobilized capture reagent is held in a capillary flow cell, embedded in a lens, and backed by a reflective surface. Excitation and emission collection is via a conventional epi-illumination filter design. The high local concentration of ligand in the capture column allows efficient and rapid capture of solution antibody. The concentration of the solution antibody in the small volume of the flow cell, coupled with the extremely efficient optical system design, results in very sensitive detection capabilities. Finally, the kinetic exclusion assay principle avoids the competition inherent in typical small ligand immunoassays. These features combine to create a system with much better performance than current technologies. In a direct comparison to ELISA assays, using the same reagents, an independent researcher found the KinExA technology to be 10 to 1000 times more sensitive, with faster time to results (see Blake, DA *et. al* (2001) *Analytica Chimica Acta*; 444, 3-11).

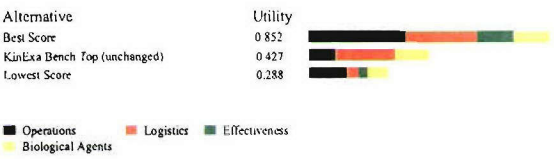
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

KinExA Bench Top ranked in the bottom third of all evaluated products for analytical laboratories and earned 18% of the utility points of the best score.

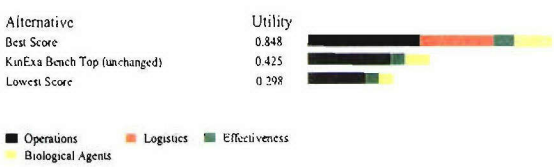
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

KinExA Bench Top ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.

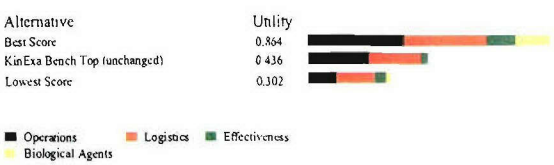
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

KinExA Bench Top ranked in the bottom third of all evaluated products for mobile laboratories and earned 50% of the utility points of the best score.

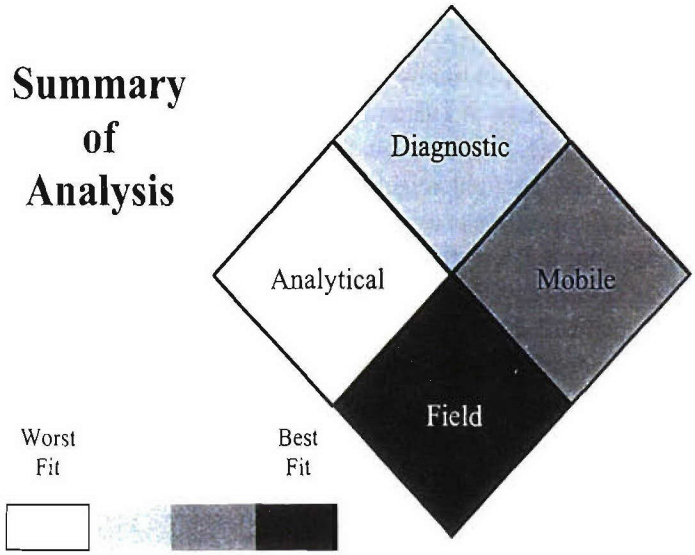
Field Use Ranking



Preference Set = Field Use

KinExA Bench Top ranked in the bottom third of all evaluated products for field use and earned 50% of the utility points of the best score.

Summary of Analysis



KinExA Bench Top Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 3 components
- Requires a buffer rinse between similar samples on the same line, weekly rinse and monthly rinse

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System can always interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Maintenance:
- 2 consumables or expendables needed
- More often than every 6 months service required
- Expected life is greater than10 years
- No daily quality assurance procedures required

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life unknown

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at 25°C to 45°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $unknown/sample
$20,000.00/system or device

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KinExA Handheld

by Sapidyne Instruments Inc.

Description: The KinExA (Kinetic Exclusion Assay) Handheld instrument is currently in development in collaboration with Dr. Diane A. Blake at Tulane University School of Medicine. The handheld is based on the same technology as the KinExA 3000, but in a lightweight, portable format. Developmental experiments using the Handheld are investigating its application for the detection of heavy metals in solution utilizing antibodies developed by Dr. Blake. The beta unit of the handheld is controlled by a hand held computer for ease of transport, field operation, and data transfer.

No Formal Detection Assay Available

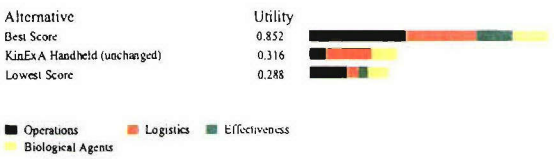
Technology: The KinExA handheld is a portable, general-purpose flow fluorimeter. The detection technology is based on capture of the free antibody or receptor on an immobilized ligand column. Excitation and emission collection is via a conventional epi-illumination filter design. As the sample is passed over the capture reagent, free receptor or antibody is captured and subsequently detected with a fluorescently labeled secondary antibody.

Analytical Laboratory Ranking

Preference Set = Analytical Laboratory

KinExA Handheld ranked in the bottom third of all evaluated products for analytical laboratories and earned 11% of the utility points of the best score.

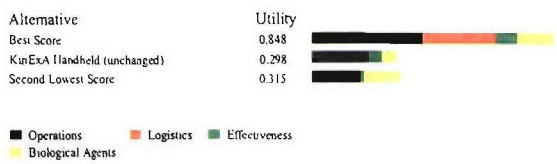
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

KinExA Handheld ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 37% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

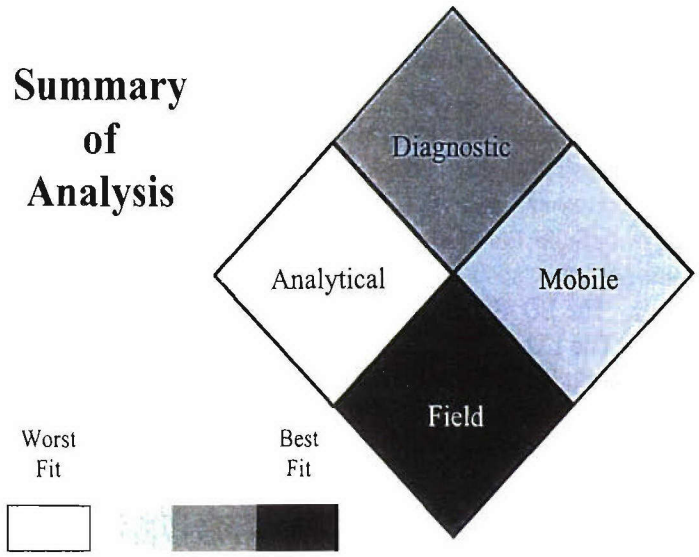
KinExA Handheld ranked in the bottom third of all evaluated products for mobile laboratories and earned 35% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

KinExA Handheld ranked in the bottom third of all evaluated products for field use and earned 38% of the utility points of the best score.

Summary of Analysis



KinExA Handheld Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 4 components
- May requires a buffer rinse between similar samples on the same line, weekly rinse and monthly rinse

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- NA to interpret raw data or call a positive through internal software
- Unknown if assay is capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or approach is not amendable to automation

Maintenance:
- 4 consumables or expendables needed
- Unknown service required
- Expected life unknown
- Unknown daily quality assurance procedures required

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Training/Speed/Manpower:
- An afternoon of training
- Greater than 20 minutes required for set-up
- 3-5 manual steps required for detection

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life unknown

Operational conditions:
- Operated temperature unknown
- Components must be stored at 4°C
- Unknown if performance of the device or system is influenced by relative humidity

Cost: $unknown/sample
Projected $5,000.00/system or device

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steve@sapidyne.com rmark@sapidyne.com

LD 400 Luminescence Detector

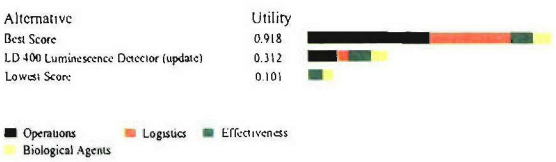
by Beckman Coulter, Inc.

Description: The LD 400 Luminescence Detector is intended to be used primarily for luminescent research applications, but it can also perform photometric measurements as well. Typical assays that can be performed include flash and glow assays, dual luciferase assays, reporter gene and toxicity assays, ATP and biomass assays, DNA assays, cellular function assays and colorimetric immunoassays, such as ELISAs and protein quantification assays. The LD 400 is capable of measuring assays in 96 well plates. The LD 400 can perform measurements in multiple modes including single wavelength, dual wavelength, photometric and luminescent kinetic, and linear scan. Full programming and data analysis are available either through powerful on-board software or via the use of a remote PC and software.

Technology: The LD 400 Luminescence Detector employs a controlled tungsten halogen lamp as a light source and a photon counting PMT as the detector for measuring light in the 300-700nm (luminescence) and 405 – 690nm (absorbance) wavelength range. It employs the use of filters to select specific wavelengths to measure, and has a luminescent dynamic range >8 decades. In addition, the LD 400 features programmable shaking and two built-in dispensers for accommodating various types of reactions.

No Formal Detection Assay Available

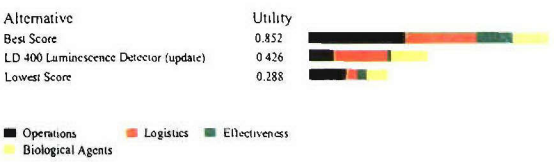
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

LD 400 Luminescence Detector ranked in the bottom third of all evaluated products for analytical laboratories and earned 34% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

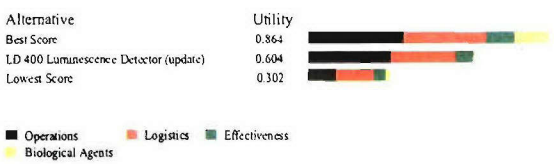
LD 400 Luminescence Detector ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 50% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

LD 400 Luminescence Detector ranked in the bottom third of all evaluated products for mobile laboratories and earned 55% of the utility points of the best score.

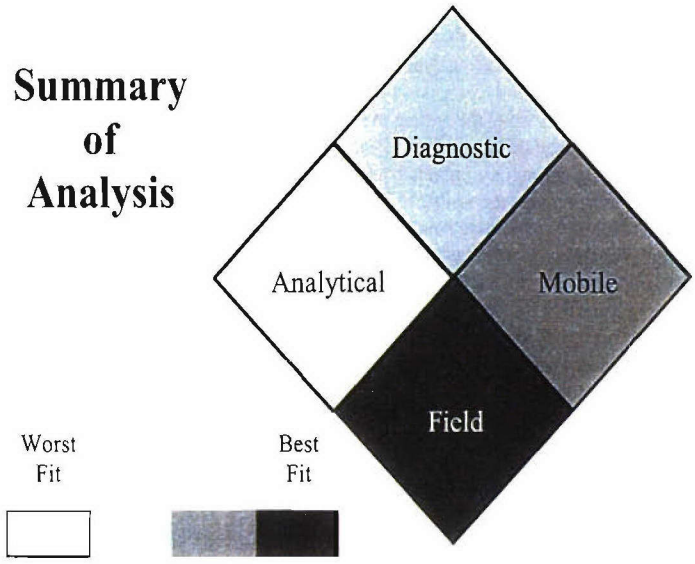
Field Use Ranking



Preference Set = Field Use

LD 400 Luminescence Detector ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

Summary of Analysis



LD 400 Luminescence Detector Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- NA solutions or buffers used
- 3 component
- Tubing cleaning required once a week

Maintenance:
- 2 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- NA shelf life

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- NA storage of components
- Device or system has peak performance at normal relative humidity conditions only

Cost: $unknown/sample
$13,995.00-17,995.00/system or device

Beckman Coulter, Inc.
4300 N. Harbor Blvd. Box 3100
Fullerton, CA 92834
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fax.(714) 773-6690
mmkelly@beckman.com

LightCycler

by Roche Applied Science

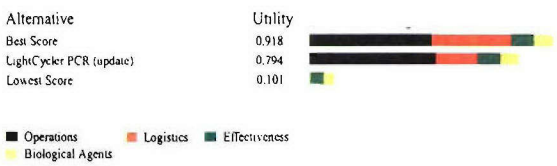
Description: The LightCycler is a Real-Time PCR machine used for rapid detection and analysis of DNA and RNA targets. Targets are both detected and quantified within 35 to 40 minutes using the system in a real-time manor without additional down stream analysis. Running gels for confirmatory testing is eliminated due to Melting Curve Analysis which makes it possible to analyze the quality and type of Nucleic acid being detected as compared to controls. PCR detection is very specific using the LightCycler with FRET Probe chemistries. The LightCycler is a flexible instrument with the ability to detect nucleic acids using SYBR Green, Hybridization Probe Chemistry and TaqMan Chemistry. Target detection sensitivity levels are down to 10 starting copies. The LightCycler is used for the detection of Anthrax with the Roche LightCycler-*Bacillus anthracis* Detection kit or with other anthrax assays. Other uses include the detection of DNA and RNA viruses and the detection of bacteria nucleic acid.

Able to Detect the Following Organisms:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (4)
Smallpox virus (4)
Orthopox virus (4)
Botulinum toxin A (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The LightCycler uses air for rapid PCR temperature cycling. A heating coil controlled by thermocouples in a single well thermal chamber is used for heating, cooling is accomplished by using a fan system to eject hot air and bring ambient air into the thermal chamber. The design insures a programmed temperature accuracy of 0.3°C with temperature ramping rates of 20°C per second. Amplification cycles take a little as 30 seconds per cycle. PCR reactions take place in specially designed borosilicate glass capillaries, which hold up to 20ul of sample. The capillaries have a high surface to volume ratio for rapid sample heating and cooling. Detection of specific Nucleic Acid sequences is achieved using FRET Probe chemistry, either Hybridization Probe chemistry or TaqMan chemistry. The PCR products are detected using an optical system with three filters. All three filter channels are recorded during each run. The Excitation of the chemical dyes is achieved by using a Blue Light LED. Qualitative analysis of PCR products is possible using a unique feature called Melting Curve Analysis (MCA). All PCR products have a specific Tm (melting point) by which they can be identified. Small differences in Tm are easily determined using MCA. This allows a sample to be analyzed for small genetic variations such as point mutations, for a more specific genetic analysis of the target sample. Results are available on a computer and analysis takes as little as one minute. Positive results can be achieved from samples with as little as 10 copies of target nucleic acid.

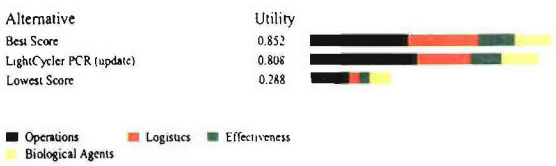
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

LightCycler ranked in the top third of all evaluated products for analytical laboratories and earned 86% of the utility points of the best score.

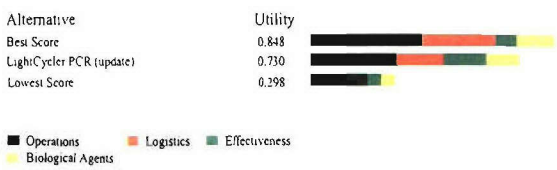
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

LightCycler ranked in the top third of all evaluated products for diagnostic laboratories and earned 95% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

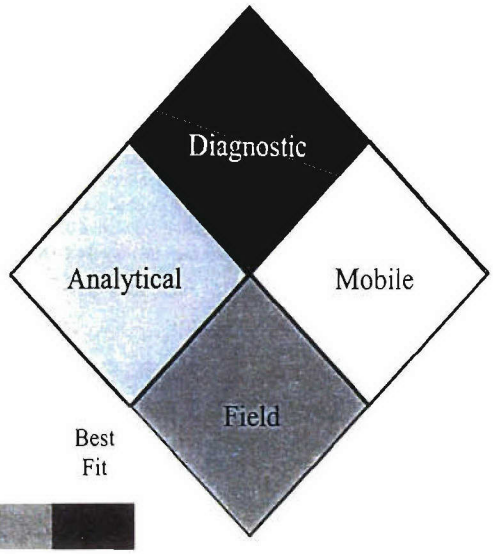
LightCycler ranked in the top third of all evaluated products for mobile laboratories and earned 86% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

LightCycler ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

Summary of Analysis



Worst Fit

Best Fit

LightCycler Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation step required
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two biological agents or toxins within the same test
- Two additional pieces of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be frozen
- Performance of the device or system is not influenced by relative humidity

Cost: $2.38/sample
$53,500.00 GSA, $57,500.00 non-GSA price/system or device

Roche Applied Science
9115 Hague Rd., P.O. box 50414
Indianapolis, IN 46250-0141
www.roche-applied-science.com

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mary.pingitore@roche.com

LightTyper

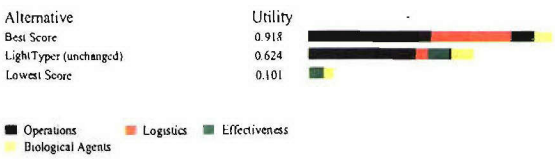
by Roche Applied Science

Description: The LightTyper is a High through-put Genetic Analysis System which uses Melting Curve Analysis to identify and genotype Genetic Sequences in PCR reactions. PCR reactions are preformed on a traditional block style thermal cycler in either a 96 or 384 well format. Fluorescent probes are included in the PCR reaction. After PCR is completed, the PCR sample trays are placed into the LightTyper. In 8 minutes the samples are melted and fluorescent data collected from all samples. Data analysis can be conducted on the computer or data can be down loaded to a LIMS system. Data Analysis using the Call-It software will make allele calls for each sample. Samples are identified by their melting their Melting Temperature (Tm).

No Formal Detection Assay Available

Technology: The LightTyper uses a CCD camera and an LED light source of 470nm which makes this a robust system. There are two long filters of 510nm and 600nm. The Temperature dynamic range is 40 to 98°C. The temperature ramp rate is 0.5 – 0.20°C. Run times range from 6 to 15 minutes. Images are acquired at 0.4 to 10 acquisitions/second. Thermal uniformity is 0.4°C. Two fluorescent chemistry can used on the LightTyper; the Hybridization Probe chemistry and the Single Probe chemistry. Software in included with the system for Probe and PCR primer design for both chemistries. The Hybridization Probe chemistry is a well known FRET chemistry which uses two fluorescent dyes and two oligo probes which must hybridize on the DNA sequence of interest for detection. The Single Probe chemistry uses a probe, which consists of one oligo with a linker and attached fluorescent dye. When the probe is bound to the DNA target sequence it will fluoresce. When unbound (melted) the probe does not fluoresce. The change is fluorescence in a sample is the basis of the identification of the PCR sample for both chemistries.
Melting Curve fluorescent profiles are collected for all samples and converted to melting peaks using the Analysis Software. The Tm for the peaks is used to make sample identification calls. The calls can be made automatically by the software. Autodetection of probe Tm shifts can be done for shifts of 2.0°C or greater.Applications for the system include Sequence Identification, SNP (Single Nucleotide Polymorphisms)Analysis, small deletion and insertion mutation analysis.For sample tracking a bar-code reader is included. Other items included are a Pentium 4 computer with 1.8 GHZ, 512 MB DDR, 40GB HD, CDRW and 17 inch flat screen monitor. Color Printer also included. The system is LIMS ready.

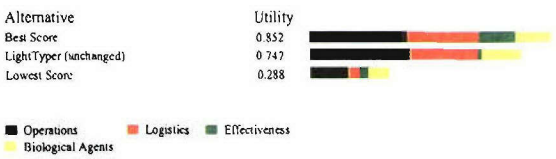
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

LightTyper ranked in the middle third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.

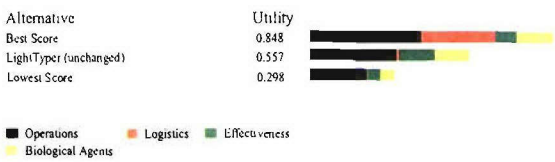
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

LightTyper ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.

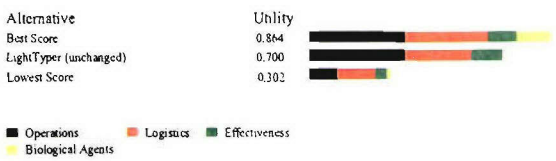
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

LightTyper ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.

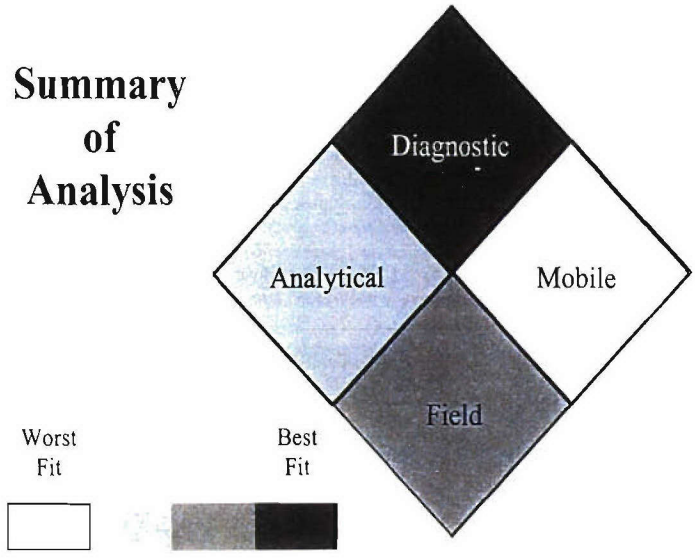
Field Use Ranking



Preference Set = Field Use

LightTyper ranked in the middle third of all evaluated products for field use and earned 81% of the utility points of the best score.

Summary of Analysis



LightTyper Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted to a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Cannot view results "in real time"
- Single centrifugation step required
- No shaking or vortexing steps
- System is sometimes able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: less than $0.50/sample
$45,000.00/system or device

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9115 Hague Rd., P.O. box 50414
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(301)482-1315 fax
mary.pingitore@roche.com dawn.coster@roche.com

Luminex 100 with X-Y Platform

by Luminex Inc.

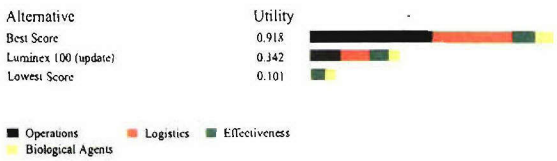
Description: The Luminex[100] assay system is a cheaper, less complex flow cytometer. The system consists of an analyzer, a computer, printer, software, and reagents. The system can be used for virtually any bioassay that is based on the specific binding of one molecule to another. Bioassays are conducted on the surface of a specifically colored polystyrene microsphere in which a capture ligand has been attached using any of a variety of different surface chemistries. The binding of the analyte to this capture bead is detected via a detection reagent labeled with a third fluorochrome. The instrument employs two different lasers, a photodiode, and a photomultiplier tube to analyse and separate the fluorescent signal on the surface of the different colored beads as they pass thru the optics. Results are displayed in real time. Currently there are 100 different microsphere sets available, each of which can be coated with a different ligand. Thus, in theory, up to 100 different analytes are be simultaneously measured in a single tube or microplate well.

Able to Detect the Following Organisms:
Bacillus anthracis (1)
E. coli 0157:H7 (1)
MS-2 bacteriophage (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The Luminex[100] Analysis System (Luminex, Inc) is a rapid assay system that reportedly can simultaneously perform up to 100 tests on a single sample. It incorporates three familiar technologies; bioassays, microspheres, and fluorescence. The system consists of a flow cytometer with a specific digital signal processing board and control software. Assays occur in solution thus allowing for rapid reaction kinetics and shorter incubation times. Capture antibodies or ligands are bound to microspheres labeled with two spectrally distinct fluorochromes. By adjusting the ratio of each fluorochrome, microspheres can be distinguished based on their spectral address. Luminex currently offers 100 different microsphere sets, each of which can be used for the simultaneous measurement of a different antigen. Bioassays are conducted on the surfaces of these microspheres. Detector antibodies are labeled with any of a number of different green fluorescent dyes. This detector-bound fluorochrome quantifies the extent of interaction that has occurred at the microsphere surface, i.e. detects antigen in a typical antigen detection assay. The instrument employs two lasers, one for the detection of the microsphere itself, and the other for the detector. Microspheres are analyzed individually as they pass by 2 separate laser beams and are classified based on their spectral address and quantified in real time. Thousands (20,000) of microspheres are processed per second resulting in an assay system theoretically capable of analyzing up to 100 different reactions on a single sample in just seconds. The manufacturer reports assay sensitivities in the femtamole level, dynamic range of 3 to 4 logs, and claim results are highly consistent and reproducible. Because the intensity of the fluorescent label is read only at the surface of each microsphere, any unbound reporter molecules remaining in solution does not affect the assay, making homogeneous assay formats possible. The system can utilize tubes as well as 96 and 384 well plates and can be automated. Many multiplexed assay kits are commercially available from a number of different manufacturers for various cytokines, phosphoproteins and hormones, but none for biological warfare agents.

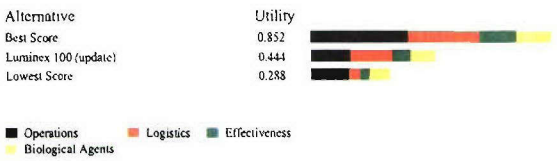
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Luminex 100 ranked in the bottom third of all evaluated products for analytical laboratories and earned 37% of the utility points of the best score.

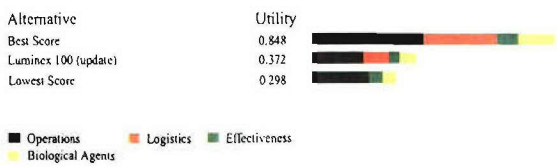
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Luminex 100 ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 52% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

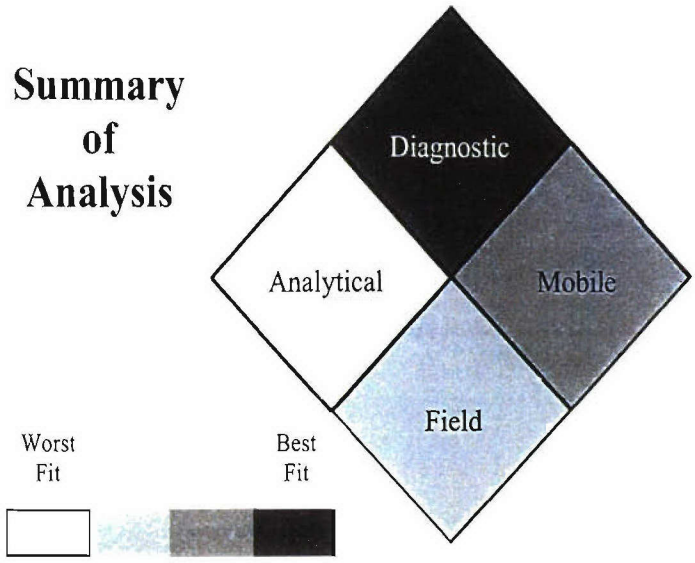
Luminex 100 ranked in the bottom third of all evaluated products for mobile laboratories and earned 44% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

Luminex 100 ranked in the bottom third of all evaluated products for field use and earned 40% of the utility points of the best score.

Summary of Analysis



Luminex 100 Evaluation Criteria Provided by Vendor

Sensitivity:
- Greater than 100,000 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- Single shaking or vortexing step
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- More than a day of training
- Greater than 20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- More often than every 6 months service required
- Expected life is 3-5years
- 10-20 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- Between 25 and 50 kg
- Shelf life between 6 months and 1 year

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

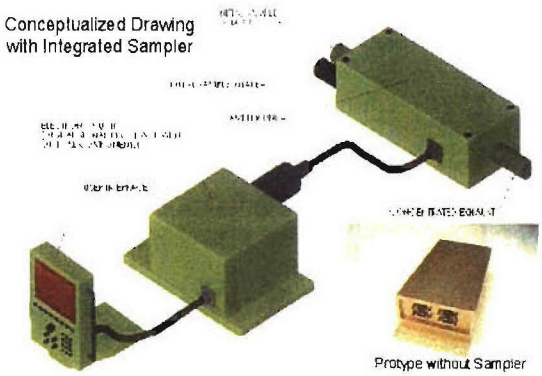
Cost: $Unknown/sample
$32,000.00/system or device

Luminex Inc.
12212 Technology Blvd.
Austin, TX 78727-6115
www.Luminexcorp.com

Point of Contact: Sales Department
(888) 219-8020
fax. (512) 219-5195

Lunascan Biodetection System

by Luna Innovations



Description: The Lunascan Biodetection system is a multi-platform measurement device that will reduce false-positives through independent, confirmation of binding events. Requiring multiple platforms to simultaneously return a positive response before triggering a detection warning will address background interference effects that may be more prevalent for a particular detection technique. The Lunascan Biodetection system is based upon optical fiber technology licensed from Lucent Technologies and patented by Luna Innovations. The detection system has been designed to integrate with field portable instrumentation and be capable of detecting multiple agents in soil, water, biological fluids, or air. Tests are currently performed in a semi-automated process with results available in less than ten minutes. Results have been recorded for simulants including BG, ovalbumin, and MS2.

Able to Detect the Following Simulants:
Bacillus globigii (1)
MS-2 bacteriophage (1)
Ovalbumin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

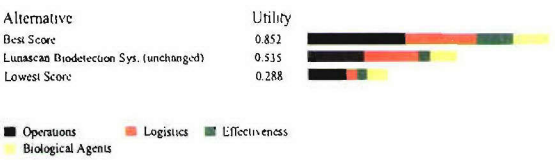
Technology: The Lunascan platform utilizes direct detection optical fiber technology coupled with fluorescence detection to determine the presence of biological warfare agents. Optical fiber sensors are ideal for field portable applications because they are small, lightweight, and rugged. Specifically, the system works by binding a target to an affinity film that has been coated to the fiber surface. Luna systems have been flight qualified and initial performance demonstrated using biological simulants such as BG, MS2, and ovalbumin. For direct detection, patented long-period grating (LPG) technology is used. The LPG is a spectral loss element that scatters light out of an optical fiber at a particular wavelength based in part on the refractive index of the surrounding environment. Therefore, the technique is not based on spectroscopy or absorption and is immune to background fluorescent effects. LPG-based biological sensors operate with specially designed affinity films that cause selective, quantitative changes in the refractive index 'seen' by the LPG in the presence of target molecules. As the coating absorbs target molecules the refractive index changes, causing a shift in the wavelength of the scattered light. This wavelength change is demodulated to determine target concentration enabling real-time monitoring of environmental conditions. The LPG sensor can be packaged with fluorescent probes to demonstrate orthogonal detection. The fluorescent probe is also based on optical fibers and uses a tag coupled to a target captured on an affinity film on the fiber surface. Light from the optical fiber excites the tag, which fluoresces. The resulting light is then captured and the intensity measured to determine concentration. Results of detection will be produced within 10 minutes for multiple targets. Audio and visual alarms can be provided.

Analytical Laboratory Ranking

Preference Set = Analytical Laboratory

Lunascan Biodetection System ranked in the bottom third of all evaluated products for analytical laboratories and earned 48% of the utility points of the best score.

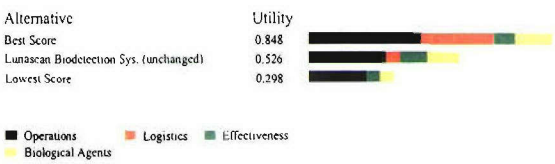
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Lunascan Biodetection System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 63% of the utility points of the best score.

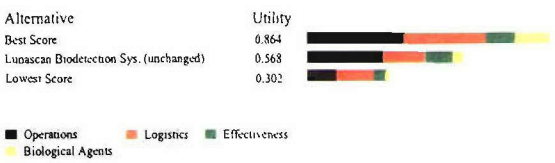
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Lunascan Biodetection System ranked in the middle third of all evaluated products for mobile laboratories and earned 62% of the utility points of the best score.

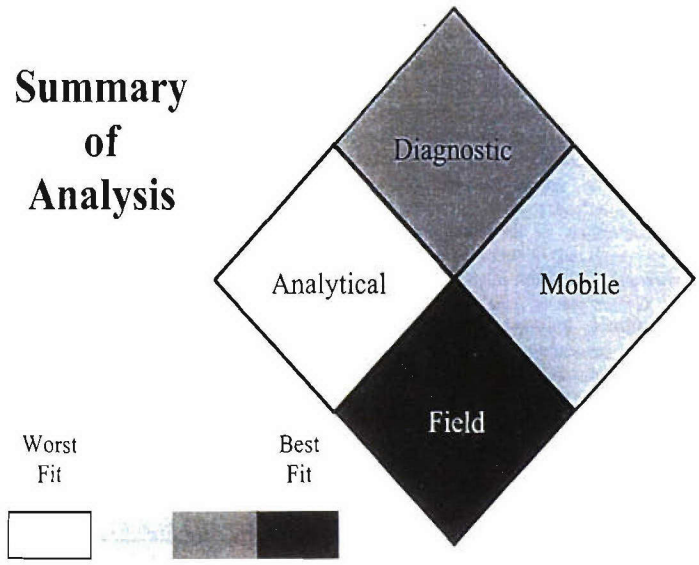
Field Use Ranking



Preference Set = Field Use

Lunascan Biodetection System ranked in the middle third of all evaluated products for field use and earned 66% of the utility points of the best score.

Summary of Analysis



Lunascan Biodetection System Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity Gauge:
- Only one incomplete device or system exist (bread board)

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- NA expected life
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 4°C and at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: Approx. $3.00/sample
$60,000.00/system or device

Luna Innovations
2851 Commerce Street
Blacksburg, VA 24060
www.lunainnovations.com

Point of Contact: Ben Plowman
(770) 315-3115
fax. (540) 961-0760
plowmanb@lunainnovations.com

MAGIChip

by Johns Hopkins University Applied Physics Laboratory

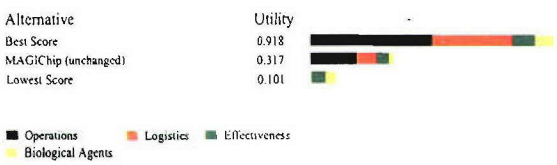
Description: The technology described here is not a PCR system but an alternative approach to multiplexed bacterial identification. A bacterial biochip prototype has been developed to address these issues. The prototype consists of a microarray based on ribosomal sequences. Multiple probes are developed for unique areas of both 16S and 23S ribosomal sequences in order to discriminate bacteria not only at the genus and species level, but using all levels of the phylogenetic tree. This redundancy provides a greater degree of confidence in the identification as the correct pathway to an identification must be consistent throughout the analysis. For example, if an unknown and unculturable microorganism presented to the biochip has a low G/C content or is not gram positive, it is not possible to be misidentified as *Bacillus anthracis* even though the unknown may have some sequence similarity to specific *Bacillus anthracis* probes. In addition, the assay described herein is rapid and has a low possibility of artifactual results due to sample manipulations following extraction. Since ribosomal RNA is present in many copies per bacterial cell, PCR is not necessary to amplify the signal output. As all live cells and spores have ribosomal RNA, there is always a detectable signal. This is unlike PCR where identifications are often made by absence of signal. If the sequence is not present in the genome of the bacteria undergoing PCR, the signal is negative, leaving the investigator to determine whether matrix effects could have interfered with the reaction or whether the sample is a true negative. Finally, and perhaps most important in any new technology, the biochip format is extremely amenable to integration with current gold standard methods such as PCR or immunological assays. The current biochip has been developed for the identification of Bacillus species.

Able to Detect the Following Organisms:
Bacillus anthracis (1)
Francisella tularensis (1)
Yersinia pestis (1)
E. coli 0157:H7 (1)
Vibrio cholera (1)
Corynebacterium diptheria (1)
Burkholderia mallei (1)
Burkholderia pseudomallei (1)
Coxiella burnetti (1)
Rickettsia prowazekii (1)
Brucella species (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: MAGIChip microarray technology discriminates microorganisms from Kingdom to the species level based on single polymorphism nucleotide detection using ribosomal RNA. An adaptation of this approach also discriminates live versus dead bacterial and fungal agents. MAGIChip technology encompasses all steps from colony to signal readout and interpretation. This approach is rapid (under 1-2 hours), robust (portable, enzyme independent) and reuseable (20-50 times, thus lowering costs). The current portable reader is small, lightweight and relatively inexpensive. Each reader is composed of a laser light source for illumination of the target molecules and a computer-controlled CCD camera for recording signal output. After the initial step, all the steps in the isolation, purification and labeling of material are performed in a single column. The preparation of sample is chemically based, not enzymatically based. User confidence measures have been added and additional measures are under advanced development for individual sample quality control. This technology has been developed for identification of *Bacillus anthracis* and can be developed for additional microbial targets including viruses (orthopox family completed). MAGIChip technology will enhance and harmonize with existing PCR based identification technology. A centralized secure database and collating tools are under advanced development as part of this effort.

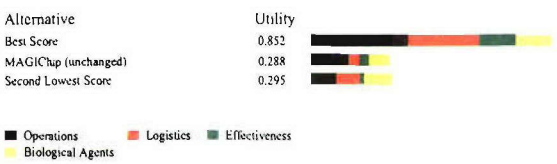
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

MAGIChip ranked in the bottom third of all evaluated products for analytical laboratories and earned 35% of the utility points of the best score.

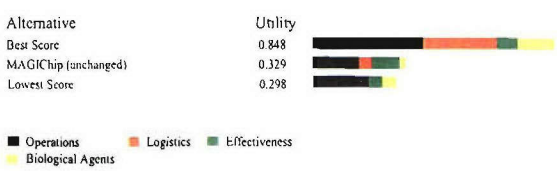
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

MAGIChip ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 34% of the utility points of the best score.

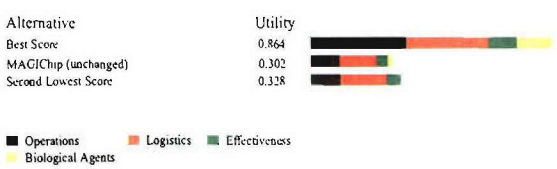
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

MAGIChip ranked in the bottom third of all evaluated products for mobile laboratories and earned 39% of the utility points of the best score.

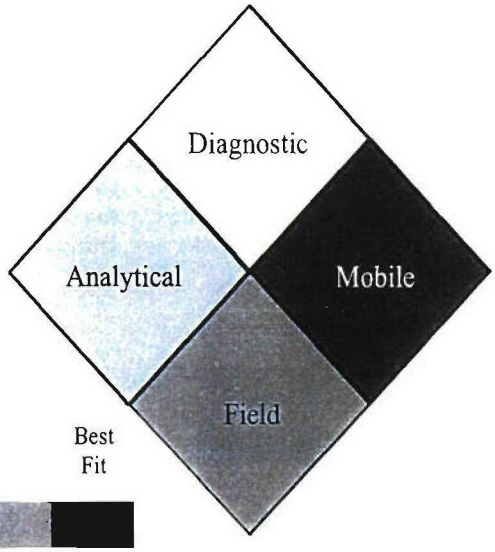
Field Use Ranking



Preference Set = Field Use

MAGIChip ranked in the bottom third of all evaluated products for field use and earned 35% of the utility points of the best score.

Summary of Analysis



MAGIChip Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110V electrical requirement or can use batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not

Throughput of product:
- Single sample detection greater than 60 minutes
- 2 samples/batch or higher
- NA volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- Less than 5 minutes required for set-up
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Unknown service required
- Expected life is 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Unknown shelf life

Ease of use/Utility
- Cannot view results "in real time"
- Multiple centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Unknown operational conditions
- Unknown components storage
- Performance of the device or system is unknown at relative humidity

Cost: $1.00-1.50/sample based on reuse of chips
$20,000.00-25,000.00/portable reader
Approx. $50.00/chip in batches of 1000

Johns Hopkins University Applied Physics Laboratory
11100 Johns Hopkins Rd., MS 2-217
Laurel, MD 20723

Point of Contact: Joany Jackman
(443) 778-8501
fax. (443) 778-6904
Joany5@aol.com

Bio Seeq Mail Sentry

by Smiths Detection – Edgewood

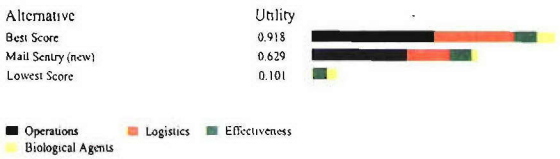
Description: The Bio-Seeq Mail Sentry is a Bio Detection system for screening mail and small parcels and is designed to provide reliable on-site mail screening capabilities. The Mail Sentry provides consistent performance and maximum reliability through it's automated, simple user-interface. All mail and parcels are processed through a sealed cabinet which minimizes exposure to the user and helps to contain the threat. Utilizing Polymerase Chain Reaction (PCR) technology, the same technology used in the U.S. Postal Service biological detection screening system, the Mail Sentry provides rapid, extremely accurate results.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (2)
Smallpox virus (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Utilizing Polymerase Chain Reaction (PCR) technology, the same technology used in the U.S. Postal Service biological detection screening system, the Mail Sentry provides rapid, extremely accurate results. The mail and packages are contained within a protective cabinet maintained under negative pressure designed to minimize agent exposure and prevent the spread of contamination. The exhaust is filtered through HEPA filters to capture aerosolized bio-agents, maximizing the safety of the mail handler operating environment.

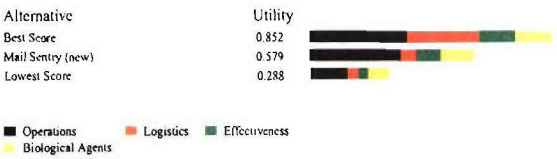
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Mail Sentry ranked in the middle third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Mail Sentry ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

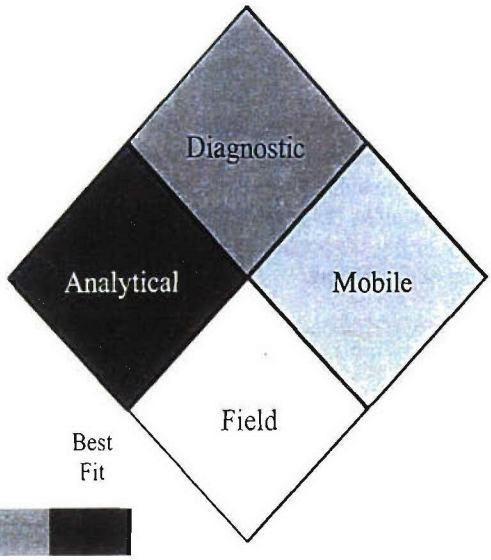
Mail Sentry ranked in the bottom third of all evaluated products for mobile laboratories and earned 51% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

Mail Sentry ranked in the bottom third of all evaluated products for field use and earned 50% of the utility points of the best score.

Summary of Analysis



Worst Fit

Best Fit

Bio Seeq Mail Sentry

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 min
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- An day of training
- Greater than 20 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 2 components
- Cleaning involves periodic rinse cycles

Maintenance:
- 0-1 consumable or expendable needed
- Needs service every six months
- Expected life measure of 5-10 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Larger than a home dishwasher
- More than 50 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $30/sample
$150,000/device or system

Smiths Detection – Edgewood
2202 Lakeside Blvd
Edgewood, MD 21040
www.smithsdetection.com

Point of Contact: David Karmel
410-510-9163
410-510-9497 fax
David.Karmel@smithsdetection.com

MAR-Magnetic Assay Reader

by Quantum Design

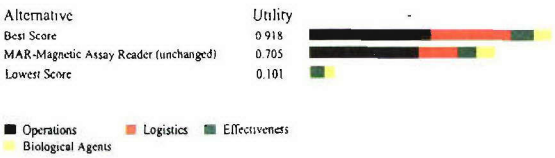
Description: The Magnetic Assay Reader (MAR) is an innovative, patented platform capable of performing a wide range of biochemical assays in the fields of medical diagnostics, chemical and biological warfare agents, and research. The MAR provides quantitative results via the detection of superparamagnetic particles (used as labels) which are bound to the analyte. Used in this manner, magnetic particle detection offers the benefits of sensitivity, speed and low cost. Additionally, it's portability opens the avenues to convenient field and point of care testing.

Able to Detect the Following Organisms/Toxin:
Bacillus anthracis (1)
Francisella tularensis (1)
E. coli 0157:H7 (1)
Orthopox virus (1)
SEB (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The MAR measures the amount of magnetic material bound to the analyte and localized in the analytical region. Three basic subsystems are employed in this detection system. A ferrite core electromagnet drives the oscillating magnetic field used to excite the paramagnetic particles to saturation, thereby ensuring maximum signal. Detection is performed by way of a mutual induction technique. The detector measures the local magnetic field expressed by the total mass of iron (as Fe3O4) in the sample. Then by way of an empirically established calibration curve, this value may be corrected to the number of molecules of analyte. Consisting of electronics, hardware and software, this subsystem provides a user-friendly interface and digital readout of data in standard ASCII files. The MAR is a uniquely suited to a wide range of point-of-care applications in the fields of medical diagnostics, food and environmental monitoring, and battlefield detection of chemical and biological agents. The flexibility of the instrument built around the fundamental MAR detection principle, gives rise to many instrument configurations as may be required by the application.

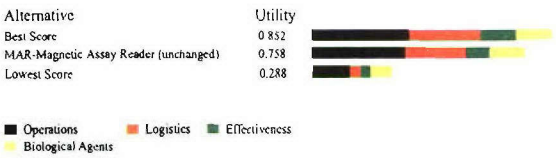
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

MAR ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

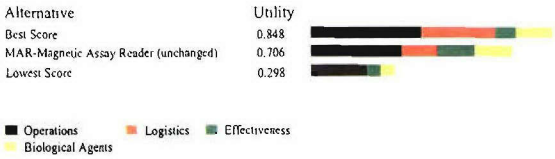
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

MAR ranked in the top third of all evaluated products for diagnostic laboratories and earned 89% of the utility points of the best score.

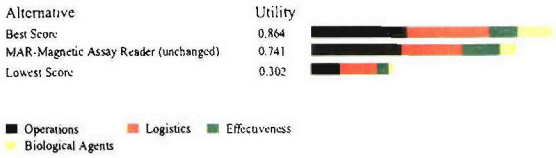
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

MAR ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.

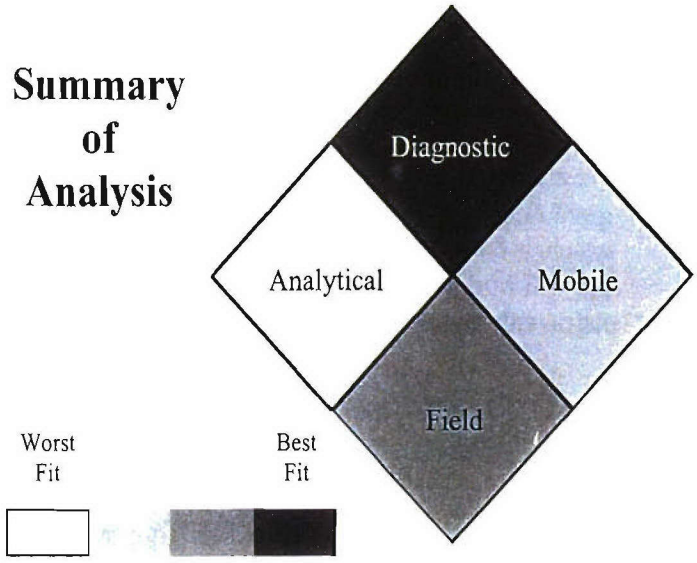
Field Use Ranking



Preference Set = Field Use

MAR ranked in the top third of all evaluated products for field use and earned 86% of the utility points of the best score.

Summary of Analysis



MAR-Magnetic Assay Reader Evaluation Criteria

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher, adaptable for more samples/batch
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- No service required
- Expected life is greater than 10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can not view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components must be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: Less than $5.00/sample
Less than $2000.00/system or device

Quantum Design
6325 Lusk Boulevard
San Diego, CA 92121
www.qdusa.com

Point of Contact: Ron Laborde
(858) 481-4400
(858) 481-7410 Fax
laborde@qdusa.com

MatriCycler

by MatriCycler, Inc.

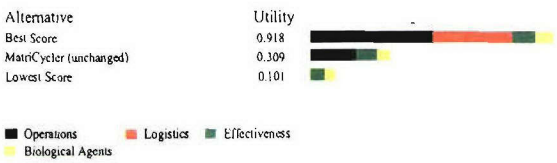
Description: The MatriCycler is a high speed high throughput thermal cycler for use in amplifying DNA, DNA sequencing, and other applications requiring rapid changes in temperature. The system is based on a new patented technology that allows for both high speed thermal cycling and high density work. The system is the only thermal cycler currently available that will work with both 384 well plates and 1536 well plates with sample volumes as low as 1 microliter.

No Formal Detection Assay Available

Technology: The MatriCycler is not a detector. It is a high throughout thermocycler for amplifying DNA samples. Please contact us directly for more information.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
MatriCycler (unchanged)	0.309
Lowest Score	0.101

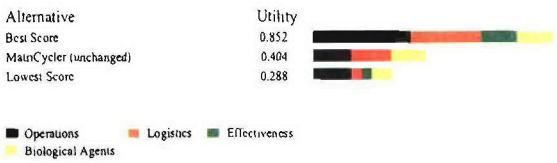


Preference Set = Analytical Laboratory

MatriCycler ranked in the bottom third of all evaluated products for analytical laboratories and earned 34% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
MatriCycler (unchanged)	0.404
Lowest Score	0.288

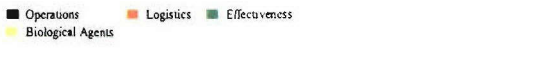


Preference Set = Diagnostic Laboratory

MatriCycler ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 47% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
MatriCycler (unchanged)	0.486
Lowest Score	0.298

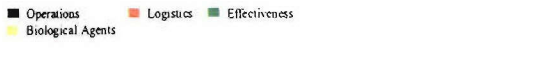


Preference Set = Mobile Laboratory

MatriCycler ranked in the bottom third of all evaluated products for mobile laboratories and earned 57% of the utility points of the best score.

Field Use Ranking

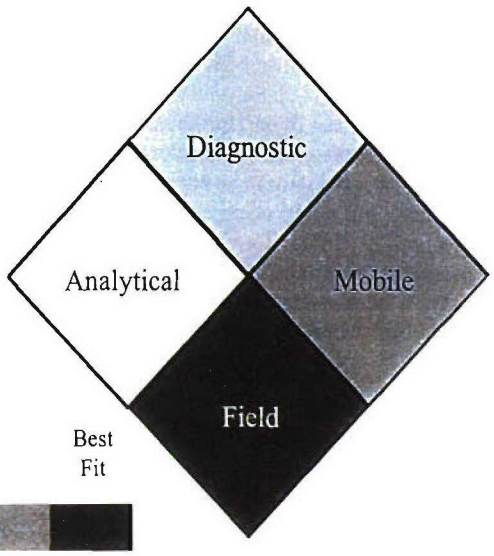
Alternative	Utility
Best Score	0.864
MatriCycler (unchanged)	0.535
Lowest Score	0.302



Preference Set – Field Use

MatriCycler ranked in the bottom third of all evaluated products for field use and earned 62% of the utility points of the best score.

Summary of Analysis



Worst Fit — Best Fit

MatriCycler Evaluation Criteria Provided by Vendor

Sensitivity:
- NA CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- NA steps required for detection

Re-use:
- Device or system is intended for single use
- NA solution or buffer used
- NA components
- NA cleaning

Maintenance:
- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 3-5 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- NA shelf life

Ease of use/Utility
- Cannot view results "in real time"
- NA centrifugation steps
- NA vortexing steps
- NA to interpret raw data or call a positive through internal software
- NA detecting multiple biological agents or toxins within the same test
- NA additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- NA components storage
- Performance of the device or system is not influenced by relative humidity

Cost: $Unknown/sample
$34,000.00/system or device

MatriCal, Inc.
665 N. Riverpoint Blvd.
Spokane, WA 99202
www.matrical.com

Point of Contact: Kevin R. Oldenburg
(509) 343-6222
fax. (509) 343-6220
Kevin.Oldenburg@matrical.com

MatriXarray

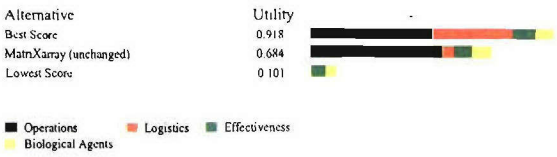
by Roche Applied Science

Description: MatriXarray is an integrated system for making Microarrays of oligonucleotides that includes software for designing Microarrays, a semi-conductor chip on which the microarray of oligonucleotides is made by in situ synthesis, a microarray synthesizer that can fit on a benchtop, and software for data acquisition and recording. With this system custom oligonucleotides microarrays can be produced within 48 hours, and users can customize the content of the chip, optimize microarray performance, and make immediate changes to microarray designs as revisions or new data appear in genomic databases. CombiMatrix oligonucleotides microarrays can be used for both gene expression and DNA Sequence identification for pathogen detection and for SNP analysis. This system allows for a large number of DNA sequences to be detected with a very small amount of sample.

No Formal Detection Assay Available

Technology: DNA sequence Detection for Pathogen Analysis starts with design of oligonucleotides arrays. Roche has a client-server based software system to manage the entire process. The microarray starts with the design of an appropriate set of capture probes. The user begins by using a target specifer software module which checks genomic databases for cross hybridization. After probes are designed the user then uses software for arranging the oligos on a microarray. The layout data is sent to the synthesizer hardware to produce the microarrays. Each microarray has up to 1000 oligo targets. Oligos are synthesized on a silicone semiconductor chip using. A highly porous three-dimensional layer is applied to the surface of the chip that greatly increases the effective surface area of an assay site. Oligo capture probes are then synthesized in the porous layer by growing DNA sequences off on an initial nucleotide base that is covalently linked to the porous layer. Using this semiconductor technology for synthesis eliminates the need for moving parts on the chip production instrumentation. The Reader Hybridizer is bench top sized and can process up to 6 chips at one time. Fluorescent labels are attached to the sample of interest for detection purposes before hybridization.

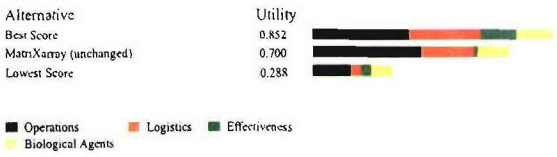
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

MatriXarray ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

MatriXarray ranked in the top third of all evaluated products for diagnostic laboratories and earned 82% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

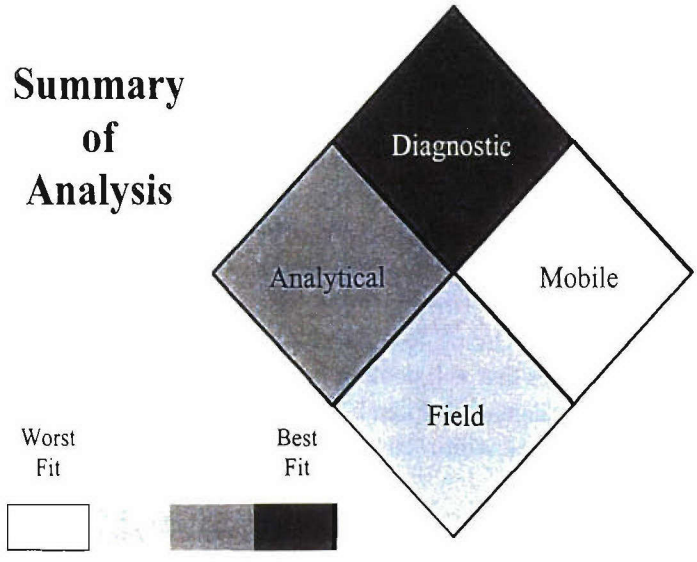
MatriXarray ranked in the middle third of all evaluated products for mobile laboratories and earned 60% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

MatriXarray ranked in the bottom third of all evaluated products for field use and earned 63% of the utility points of the best score.

Summary of Analysis



MatriXarray Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board), will be commercially available spring of 2003

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Greater than 20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- Unknown solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can not view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- Unknown if system is able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be frozen
- Performance of the device or system is not influenced by relative humidity

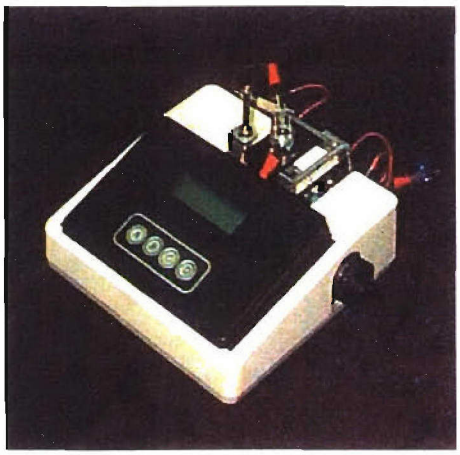
Cost: $Unknown/sample
Approx. $95,000.00/system or device

Roche Applied Science
9115 Hague Rd., P.O. Box 50414
Indianapolis, IN 46250-0141
www.roche-applied-science.com

Point of Contact: Mary Pingitore
(800) 845-7355 ext. 8015
fax. (301) 482-1315
mary.pingitore@roche.com

Microfluidic FRET Reader

by OmniSite BioDiagnostics, Inc.



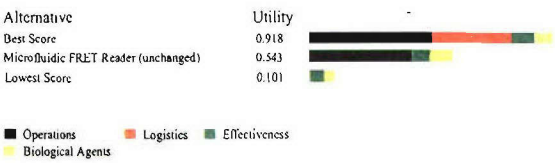
Description: This instrument is a compact fluorescence resonance energy transfer (FRET) reader, capable of rapid one-step immunoassays (without wash steps). Immuno FRET assays were developed for *Bacillus cereus* spores and *E. coli* bacteria (see **Bruno et al., Biochem. Biophys. Res. Comm. Vol. 287:875-880, 2001**). Assays are currently performed in 50 uL plastic or silicon cartridges, OmniSite is developing microfluidic cartridges that will contain freeze-dried immuno-FRET reagents that can be rehydrated by the sample and assayed within minutes.

No Formal Detection Assay Available

Technology: FRET is popular technique in the research and clinical diagnostic arenas for such popular assays as the TaqMan PCR assays, because it enables a high sensitivity "lights on" or "lights off" effect due to quenching or liberation of fluorescence with an absorbing molecule (quencher). In OmniSite's FRET format, Oregon Green dyes are quenched by QSY-7. The reader has a slider capable of holding 8 or more single assay cartridges.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Microfluidic FRET Reader (unchanged)	0.543
Lowest Score	0.101

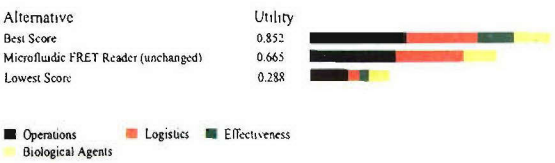


Preference Set = Analytical Laboratory

Microfluidic FRET Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 59% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Microfluidic FRET Reader (unchanged)	0.665
Lowest Score	0.288

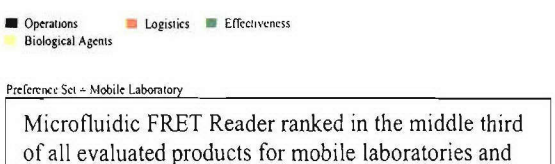


Preference Set = Diagnostic Laboratory

Microfluidic FRET Reader ranked in the middle third of all evaluated products for diagnostic laboratories and earned 78% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Microfluidic FRET Reader (unchanged)	0.563
Lowest Score	0.298

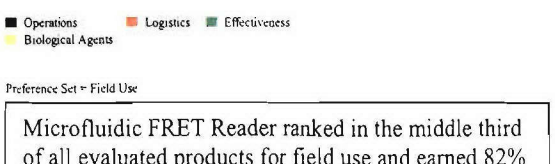


Preference Set = Mobile Laboratory

Microfluidic FRET Reader ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.

Field Use Ranking

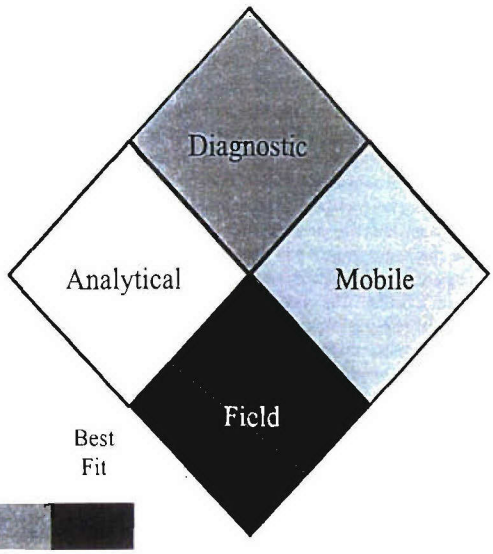
Alternative	Utility
Best Score	0.864
Microfluidic FRET Reader (unchanged)	0.705
Lowest Score	0.302



Preference Set = Field Use

Microfluidic FRET Reader ranked in the middle third of all evaluated products for field use and earned 82% of the utility points of the best score.

Summary of Analysis



Microfluidic FRET Reader Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- A few devices or system exist (brass board)

System requirements:
- System or device has 110V or battery requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is greater than10 years
- 10-20 minutes daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life greater than 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- A single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $0.10/sample
$2,000.00/system or device

OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact: John G. Bruno
(512) 479-7732 ext. 2202
fax. (512) 494-0756
bruno@spec.com

M-Series M1M

by BioVeris Corporation

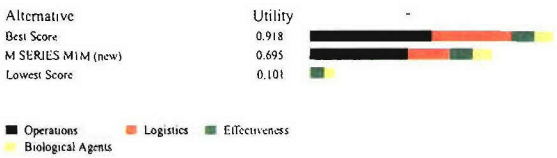
Description: The M1M is an automated analyzer designed for use with BV™ reagents. This system provides sample handling, detection based upon BioVeris™ (BV) Technology, electrochemiluminescence, and analysis in a 96-well microplate or minitube format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about 1 minute and an entire plate in approximately 90 minutes. It can also run a partial or an entire microplate in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system also checks for reagent type and reagent usage to ensure adequate supply and proper system function. The system also has the capability to dispense reagents into sample tubes or wells. An intuitive graphical software interface provides wizards to assist with plate set-up, allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review. This system has been designed to meet applicable requirements of MIL-STD 810F.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (4)
Smallpox virus (4)
Orthopox virus (4)
Botulinum toxins A, B, E (4)
Ricin (4)
SEB (4)
E. coli O157:H7 (3)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG™, the product name for ruthenium (II) tris-bipyridine. Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, o ligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagenetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

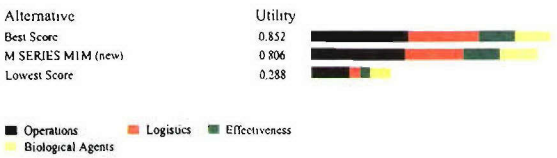
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

M1M ranked in the top third of all evaluated products for analytical laboratories and earned 76% of the utility points of the best score.

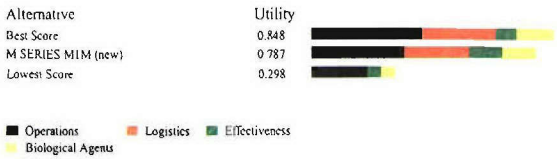
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

M1M ranked in the top third of all evaluated products for diagnostic laboratories and earned 95% of the utility points of the best score.

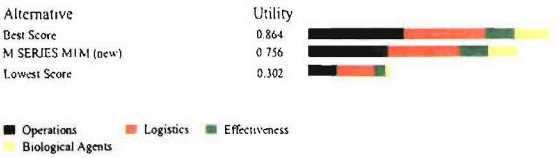
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

M1M ranked in the top third of all evaluated products for mobile laboratories and earned 93% of the utility points of the best score.

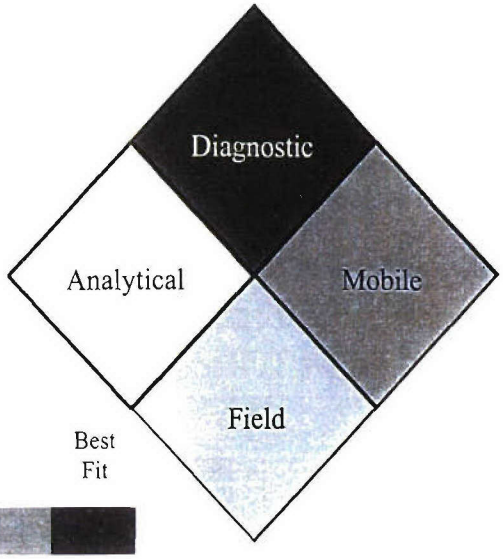
Field Use Ranking



Preference Set = Field Use

M1M ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

Summary of Analysis



Worst Fit

Best Fit

M SERIES M1 Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

Reagents available from the Critical Reagents Program Call 410-436-5562 for more information.

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- A decontamination protocol is required for use one time per week

Maintenance:
- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

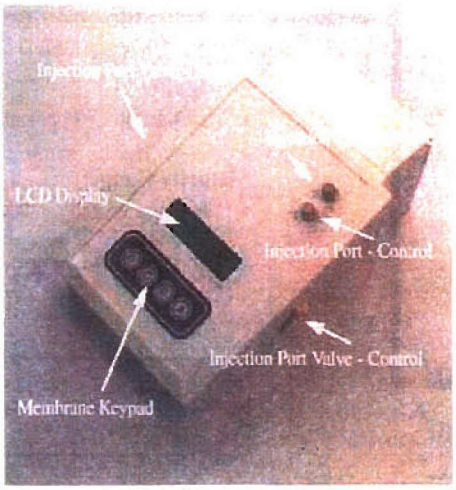
Cost: $<10.00/sample
$<50,000.00/system or device

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, MD 20877
www.bioveris.com

Point of Contact: Jill White
(301) 869-9800
fax. (240) 632-2206
jwhite@bioveris.com

Mini-PCR Fluorescence Reader

by OmniSite BioDiagnostics, Inc.

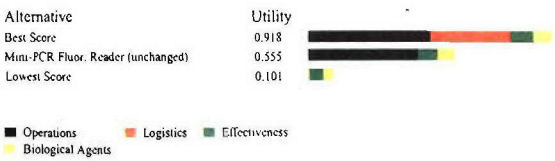


Description: This instrument combines a compact thermal cycler for PCR with an epifluorescence head to detect and measure fluorescence intensity optically through a window on a microfluidic chip. The device reads TaqMan PCR FRET assays very rapidly and detects amplification within 5 – 10 cycles of PCR, faster than comparable PCR reader such Cepheid's portable PCR reader.

No Formal Detection Assay Available

Technology: The mini-PCR FRET reader, originally funded by NASA SBIR, is designed to detect PCR amplification of TaqMan assays in shuttle craft/space station workplace where microgravity environment precludes normal liquid handling methods for innovative use of microfluidic interconnections to prevent liquid spillage. OmniSite received high ratings from NASA for this Phase II SBIR funded device and is in the process of filing two patents for the innovative microfluidic chip design and the fluid interconnects that allow rapid and facile snapping of the chip into place in microgravity environment without liquid spillage.

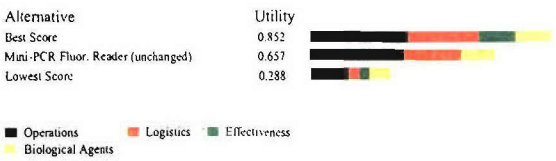
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Mini-PCR Fluorescence Reader ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

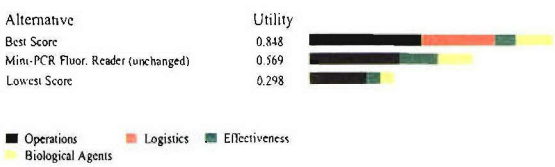
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Mini-PCR Fluorescence Reader ranked in the middle third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

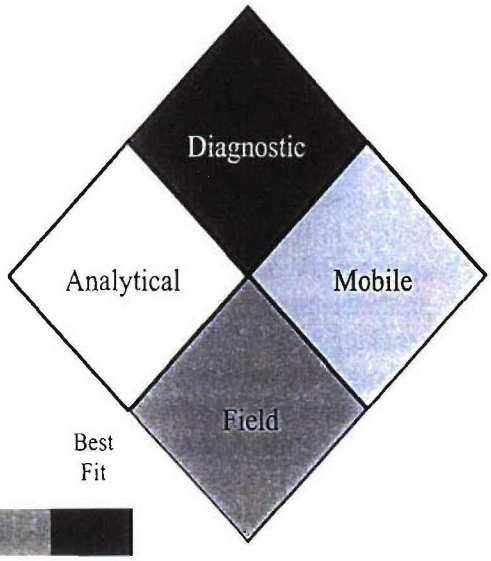
Mini-PCR Fluorescence Reader ranked in the middle third of all evaluated products for mobile laboratories and earned 67% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

Mini-PCR Fluorescence Reader ranked in the middle third of all evaluated products for field use and earned 77% of the utility points of the best score.

Summary of Analysis



Mini-PCR Fluorescence Reader Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or system exist (brass board)

System requirements:
- System or device has 110V or battery electrical requirements
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is greater than10 years
- 10-20 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be frozen
- Performance of the device or system is not influenced by relative humidity

Cost: $0.50/sample
$3,000.00/system or device

OmniSite BioDiagnostics, Inc.
101 West 6th Street, Suite 200
Austin, TX 78701

Point of Contact: John G. Bruno
(512) 479-7732 ext. 2202
fax. (512) 494-0756
bruno@spec.com

Mobile Molecular Laboratory

by MJ Research

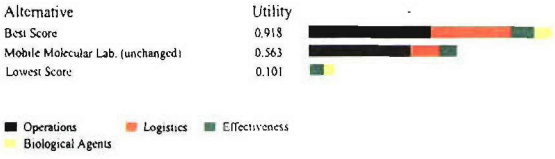
Description: The Mobile Molecular Laboratory is a professional-quality DNA laboratory in a suitcase. It is appropriate for field investigation, education, or as a quick and inexpensive way to equip a lab just beginning DNA research. It features a MiniCycler thermal cycler, microcentrifuge, mini gel box, compact power supply, compact UV transilluminator, transilluminator photodocumentation system, insulating-foam cooler, benchtop enzyme chiller, 500ml polypropylene bottles, and rugged foam-lined plastic case. All instruments feature universal power adapters and detachable cord sets and are resistant to power surges.

Able to Detect the Following Organisms/Toxin:
Bacillus anthracis (1)
E. coli 0157:H7 (1)
Orthopox virus (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The system would use PCR-based assays, which would require running out the amplification products on pre-cast gels complete with ethidium bromide; results would require interpretation by user by observing gel on transilluminator or from a Polaroid photo of gel.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Mobile Molecular Laboratory ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

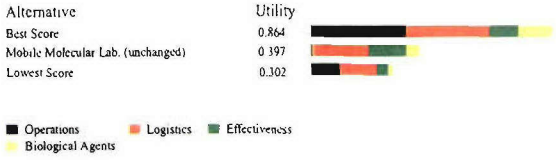
Mobile Molecular Laboratory ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 48% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

Mobile Molecular Laboratory ranked in the bottom third of all evaluated products for mobile laboratories and earned 51% of the utility points of the best score.

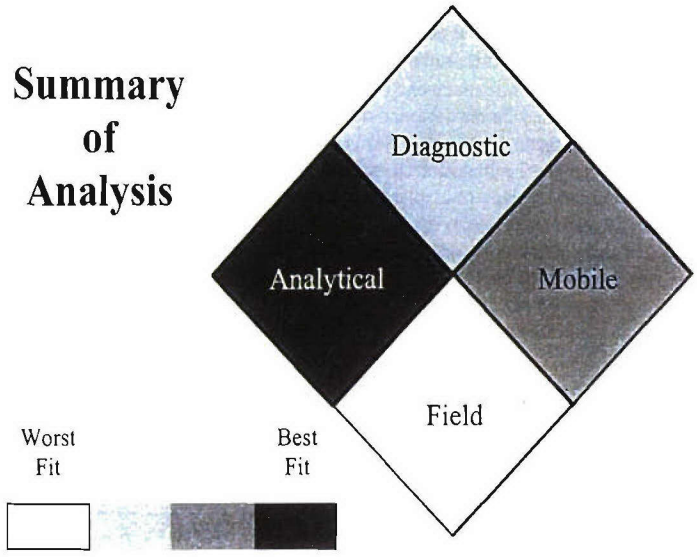
Field Use Ranking



Preference Set = Field Use

Mobile Molecular Laboratory ranked in the bottom third of all evaluated products for field use and earned 46% of the utility points of the best score.

Summary of Analysis



Mobile Molecular Laboratory Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or approach is not amendable to automation

Training/Speed/Manpower:
- More than a day of training
- Greater than 20 minutes required for set-up
- Greater than12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- More often than every 6 months service required
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life greater than 3 years if lyophilized

Ease of use/Utility
- Can not view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

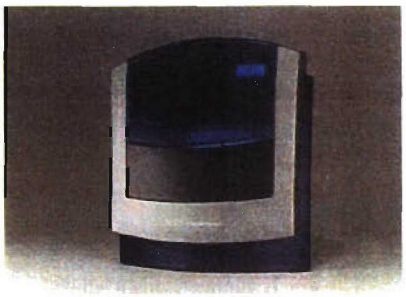
Operational conditions:
- Operated from 4°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $Unknown/sample
$6071.00 GSA price/system or device

MJ Research, Inc.
590 Lincoln St.
Waltham, MA 02451
www.mjr.com

Point of Contact: John Hansen
(617) 972-8157 ext. 8157
fax. (617) 923-8080
johnh@mjr.com

M SERIES M1R
by BioVeris Corp.



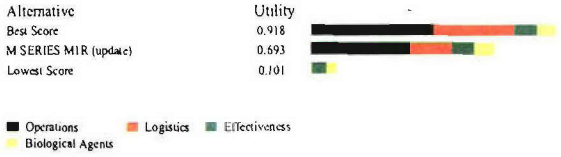
Description: The M1 is an automated analyzer designed for use with BV™ reagents. This system provides sample handling, detection based upon BioVeris™ (BV) Technology, electrochemiluminescence, and analysis in a 96-well microplate format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about 1 minute and an entire plate in approximately 90 minutes. It can also run a partial or an entire microplate in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system also checks for reagent type and reagent usage to ensure adequate supply and proper system function. An intuitive graphical software interface provides wizards to assist with plate set-up, allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review.

Technology: BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG™, the product name for ruthenium (II) tris-bipyridine. Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, oligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagenetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (3)
E. coli 0157:H7 (3)
Francisella tularensis (4)
Yersinia pestis (4)
Orthopox virus (4)
Smallpox virus (4)
Botulinum toxins A,B,E (4)
SEB (4)
Ricin (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

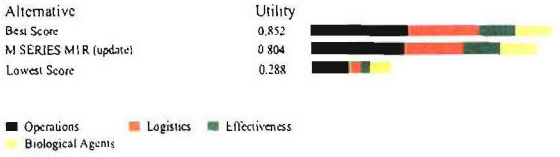
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

M SERIES M1R ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

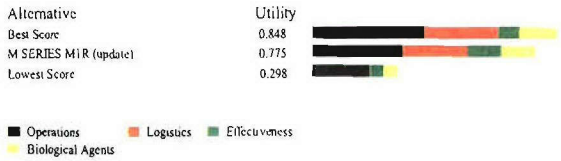
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

M SERIES M1R ranked in the top third of all evaluated products for diagnostic laboratories and earned 94% of the utility points of the best score.

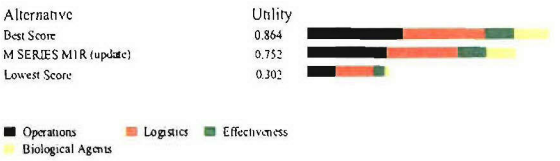
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

M SERIES M1R ranked in the top third of all evaluated products for mobile laboratories and earned 91% of the utility points of the best score.

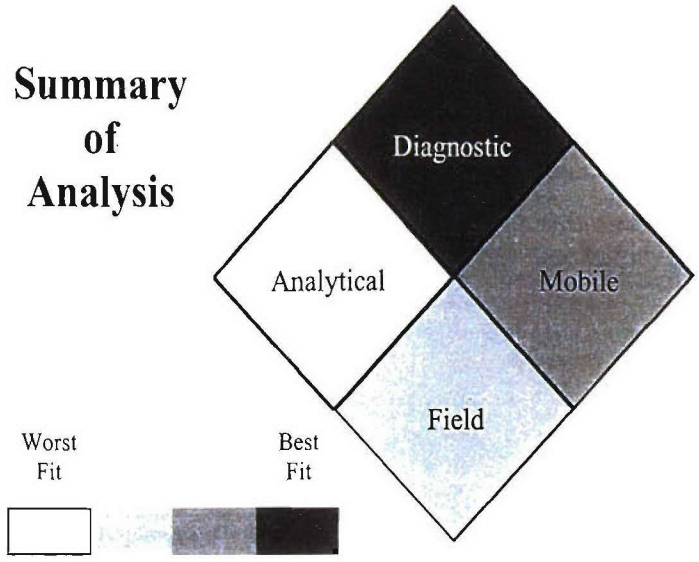
Field Use Ranking



Preference Set = Field Use

M SERIES M1R ranked in the top third of all evaluated products for field use and earned 87% of the utility points of the best score.

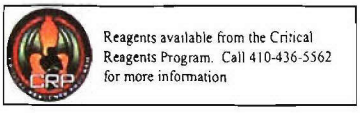
Summary of Analysis



M SERIES M1 Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available



System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- A decontamination protocol is required for use one time per week

Maintenance:
- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

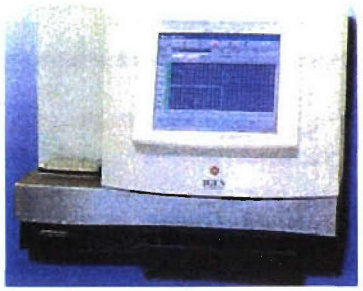
Cost: $<10.00/sample
$<50,000.00/system or device

BioVeris Corporation
16020 Industrial Drive
Gaithersburg, MD 20877
www.bioveris.com

Point of Contact: Jill White
(301) 869-9800
fax. (240) 632-2206
jwhite@bioveris.com

M SERIES M384

by BioVeris Corp.



Description: The M384 is an automated analyzer designed for use with BV™ reagents. This system provides sample handling, detection based upon BioVeris™ (BV) Technology, electrochemiluminescence, and analysis in a 96- or 384-well microplate format. This system is designed for the detection of multiple analytes, from small molecules, to proteins, to microorganisms, in a wide variety of matrices. The system processes a single sample in about 1 minute and an entire plate in approximately 12 minutes. It can also run a partial or an entire microplate in a single or multi-test mode. The instrument automatically performs a system check to ensure proper system operation on start-up. The system also checks for reagent type and reagent usage to ensure adequate supply and proper system function. An intuitive graphical software interface provides wizards to assist with plate set-up, allows for use of pre-set protocols or user determined protocols, and real-time updates of system output and data review.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (3)
E. coli 0157:H7 (3)
Francisella tularensis (4)
Yersinia pestis (4)
Smallpox virus (4)
Orthopox virus (4)
Botulium toxin A,B,E (4)
SEB (4)
Ricin (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: BV Technology uses a paramagnetic microparticle as the solid support for formation of a reaction. Multiple compounds can be labeled with BV-TAG™, the product name for ruthenium (II) tris-bipyridine Using a variety of linking chemistries, the ruthenium molecule can be directly bound to proteins, thiols, oligonucleotides, carbohydrates, and carboxyl groups using a simple labeling and purification procedure. For BV technology, ruthenium serves as the detector molecule for the system. At the core of the instrument system is a flow cell designed to measure the amount of ruthenium bound to the paramagenetic microparticles through a chemical reaction known as electrochemiluminescence. When the reaction mixture enters the flow cell, a magnet captures the microparticles on the surface of an electrode. Any components of the assay or sample that are not bound specifically to the microparticles through the assay component interactions continue past the electrode and exit the system as part of the waste stream. BV-TAG labeled species on the microparticles are detected by introducing tripropylamine (TPA) to the flow cell, applying an oxidizing potential at the electrode and measuring the integrated intensity of the emitted light. The flow cell is then washed with a cleaning solution and prepared for the next sample. For the electrochemiluminescent reaction, the system uses two bulk reagent solutions that enter the flow cell via bulk solution containers attached directly to the instrument system. The first bulk reagent, known as BV Assay Buffer contains TPA that is used in the electrochemiluminescent reaction process. The second bulk reagent is BV Cell Cleaner that is used by the system to remove the previous reaction from the flow cell in preparation for receipt of the next sample.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
M SERIES M384 (update)	0.705
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set – Analytical Laboratory

M SERIES M384 ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
M SERIES M384 (update)	0.814
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set – Diagnostic Laboratory

M SERIES M384 ranked in the top third of all evaluated products for diagnostic laboratories and earned 96% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
M SERIES M384 (update)	0.608
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set – Mobile Laboratory

M SERIES M384 ranked in the middle third of all evaluated products for mobile laboratories and earned 72% of the utility points of the best score.

Field Use Ranking

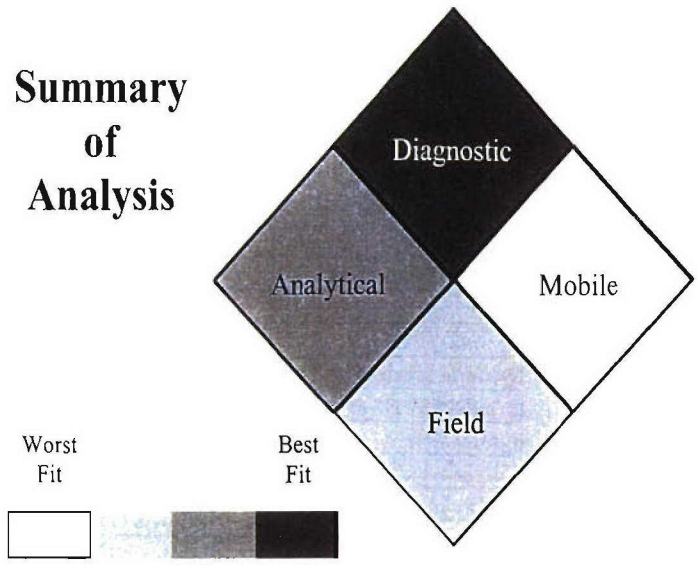
Alternative	Utility
Best Score	0.864
M SERIES M384 (update)	0.645
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set – Field Use

M SERIES M384 ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.

Summary of Analysis



M SERIES M384 Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

Reagents available from the Critical Reagents Program. Call 410-436-5562 for more information.

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 384 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 3 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Every 6 months service required
- Expected life is 5-10 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- Single shaking or vortexing step
- System is able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- One additional piece of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 25°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $<10.00/sample
$<95,000.00/system or device

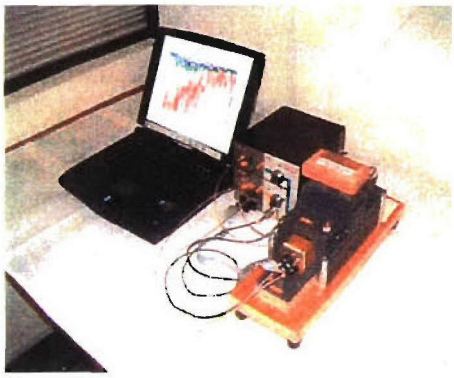
BioVeris Corporation
16020 Industrial Drive
Gaithersburg, MD 20877
www.bioveris.com

Point of Contact: Jill White
(301) 869-9800 ext. 1054
fax. (240) 632-2206
jwhite@bioveris.com

Multi-Photon Detection (MPD) Portable

by BioTraces, Inc.

Description: Multi-Photon Detection (MPD) provides the new standard of sensitivity for immunological detection, quantification and identification of pathogens. MPD technology applies to the full spectrum of BW agents: viruses, bacteria and biotoxins.



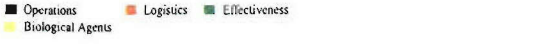
Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
Francisella tularensis (1)
Yersinia pestis (1)
Brucella species (1)
E. coli 0157:H7 (1)
Vibrio cholera (1)
Corynebacterium diptheria (1)
Burkholderai mallei (1)
Burkholderia pseudomallei (1)
Coxiella burnetti (1)
Rickettsia prowazekii (1)
Rift Valley fever virus (1)
Orthopox virus (1)
VEE virus (1)
Hanta virus (1)
Yellow fever virus (1)
Dengue fever virus (1)
MS-2 bacteriophage (1)
Botulinum toxins A,B,E (1)
SEB (1)
T-2 toxin (1)
Ricin (1)
Saxitoxin (1)
Shigatoxin (1)
Conotoxins (1)
Palytoxin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: MPD technology utilizes unique photons detection methods. This system maps photon properties and rejects all non-specific events. Coincidence is used to diminish the background by a factor of more than thousand. The "introduced" tags are specifically recognized and counted. This unique technology provides the best possible sensitivity for both the nucleic-acid based and immunological detection, including accurate identification of pathogens. This method is compatible with the development of automated air and water safety monitoring that is fast and accurate. We developed the MPD enhanced immunoassays with about 1 fg/ml sensitivity for about 10 targets. We are currently extending this technology to P-chips with MPD read-out. The proposed BW agents detection system will consist of three part: air intake/filtration sub-system, "biochemical wet chamber" and MPD based immunodetection module.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
MultiPhoton Detection Portable (unchanged)	0.708
Lowest Score	0.101

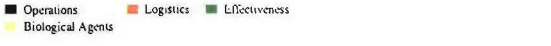


Preference Set = Analytical Laboratory

Multi-Photon Detection Portable ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
MultiPhoton Detection Portable (unchanged)	0.703
Lowest Score	0.288



Preference Set = Diagnostic Laboratory

Multi-Photon Detection Portable ranked in the top third of all evaluated products for diagnostic laboratories and earned 83% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
MultiPhoton Detection Portable (unchanged)	0.632
Lowest Score	0.298

Preference Set = Mobile Laboratory

Multi-Photon Detection Portable ranked in the middle third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

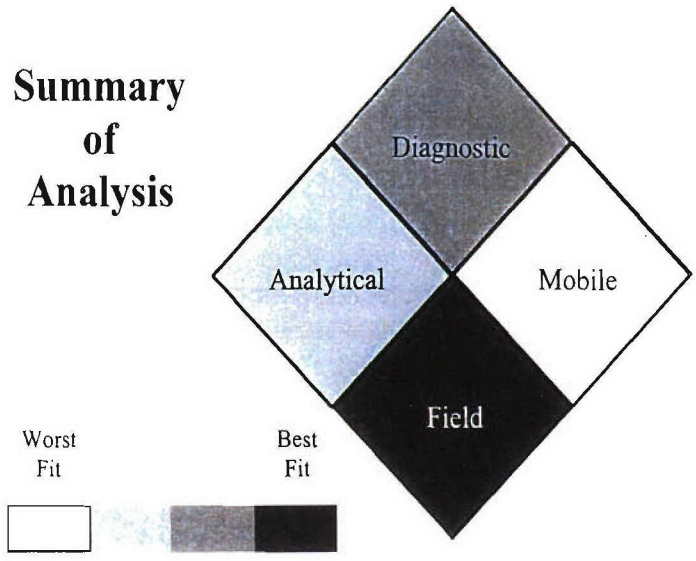
Field Use Ranking

Alternative	Utility
Best Score	0.864
MultiPhoton Detection Portable (unchanged)	0.768
Lowest Score	0.302

Preference Set = Field Use

Multi-Photon Detection Portable ranked in the top third of all evaluated products for field use and earned 89% of the utility points of the best score.

Summary of Analysis



Multi-Photon Detection (MPD) Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device uses batteries
- The system or device does require water aliquots
- The system or device does require an external air source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 2 components
- Daily extensive wash required

Maintenance:
- 2 consumables or expendables needed
- Every 6 months service required
- Expected life is 3-5 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Less than 200 BTUS generated

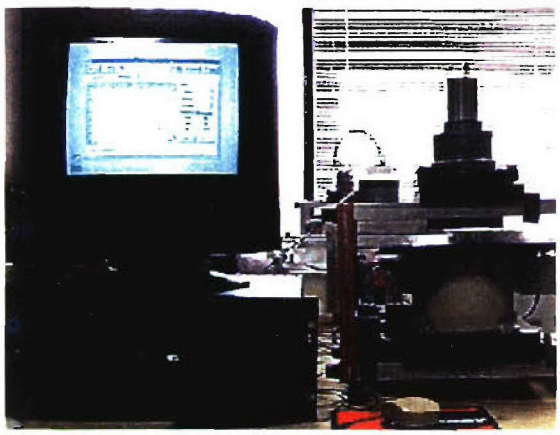
Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at room temperature or 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $1.00/sample
$30,000.00/system or device

BioTraces
13455 Sunrise Valley Drive, Suite 200
Herndon, VA 20171
www.biotraces.com

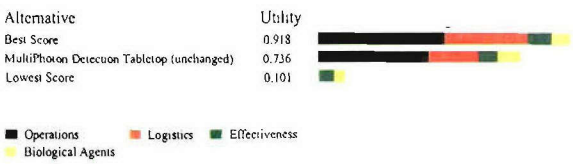
Point of Contact: A.K. Drukier
(703) 793-0907 or (703) 793-1550 ext. 108
fax. (703) 793-1564
AKD@biotraces.com

Additional Information:
Multi-Photon Detection (MPD) Tabletop Version



Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
MultiPhoton Detection Tabletop (unchanged)	0.736
Lowest Score	0.101

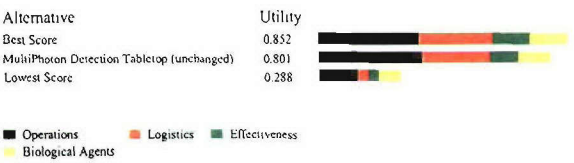


Preference Set – Analytical Laboratory

Multi-Photon Detection Table Top ranked in the top third of all evaluated products for analytical laboratories and earned 80% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
MultiPhoton Detection Tabletop (unchanged)	0.801
Lowest Score	0.288



Preference Set – Diagnostic Laboratory

Multi-Photon Detection Table Top ranked in the top third of all evaluated products for diagnostic laboratories and earned 94% of the utility points of the best score.

Mobile Laboratory Ranking

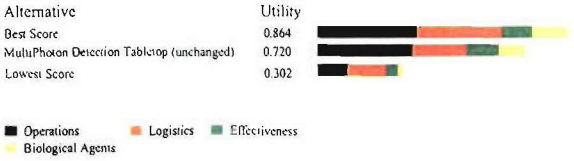
Alternative	Utility
Best Score	0.848
MultiPhoton Detection Tabletop (unchanged)	0.647
Lowest Score	0.298

Preference Set – Mobile Laboratory

Multi-Photon Detection Table Top ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.

Field Use Ranking

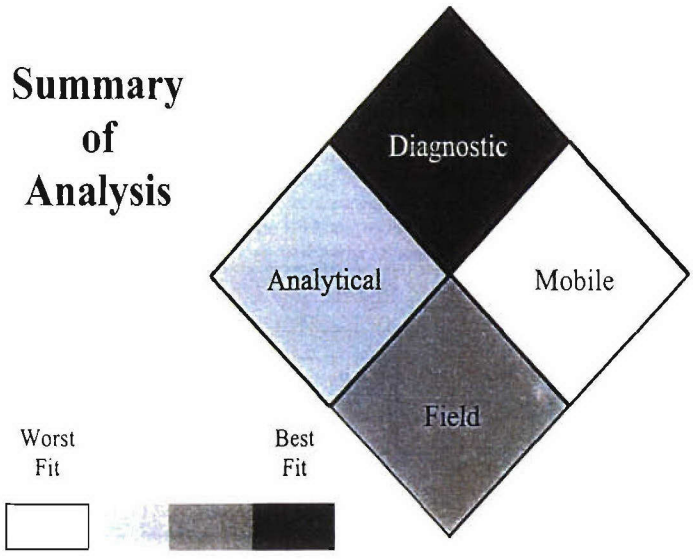
Alternative	Utility
Best Score	0.864
MultiPhoton Detection Tabletop (unchanged)	0.720
Lowest Score	0.302



Preference Set – Field Use

Multi-Photon Detection Table Top ranked in the top third of all evaluated products for field use and earned 83% of the utility points of the best score.

Summary of Analysis



Multi-Photon Detection (MPD) Tabletop Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device has 110/220V (switch able) electrical requirement
- The system or device does require water aliquots
- The system or device does require an external air source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 2 components
- Daily extensive wash required

Maintenance:
- 2 consumables or expendables needed
- Every 6 months service required
- Expected life is 3-5 years
- 5-10 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds are produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature or 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $1.00/sample
$30,000.00/system or device

BioTraces
13455 Sunrise Valley Drive, Suite 200
Herndon, VA 20171
www.biotraces.com

Point of Contact: A.K. Drukier
(703) 793-0907 or (703) 793-1550 ext. 108
fax. (703) 793-1564
AKD@biotraces.com

Mx3000P Real Time PCR System

by Stratagene Inc.

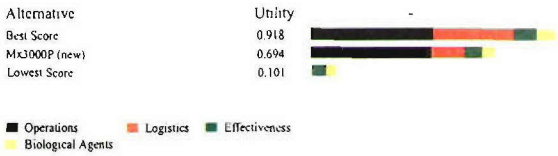
Description: The Mx3000P is a system for performing real-time quantitative PCR (QPCR). This technique allows researchers to quickly and easily quantify nucleic acids for studying gene expression, mutational analysis, disease state, gene dosage, and pathogen detection. QPCR measures PCR product accumulation during the exponential phase of the reaction and before amplification becomes vulnerable to limiting reagents and cycling variability. Fluorescent QPCR data provides accurate information on initial starting copy number. Using QPCR, amplification and detection are combined in a single step and in a single closed tube. This eliminates the need for numerous post-PCR manual steps, and reduces the possibility of introducing variability or laboratory contamination.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (4)
Brucella species (4)
Orthopox virus (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The Mx3000P can be used to detect and quantify the amount of a specific sequence DNA or RNA present as starting template prior to a PCR amplification reaction. This is done using a technique known as real-time quantitative PCR. This technology is based on the measurement of the fluorescence of either a double stranded DNA binding dye such as SYBR Green or a fluorescent dye-bound probe based system like Taqman, Molecular Beacons, or Scorpions Probes. For any of these systems, the amount of fluorescence will increase as the amount of amplified PCR product increases. Based on the cycle number in the PCR reaction where your fluorescence rises above a threshold of background fluorescence (the threshold cycle, or Ct) you can calculate how much starting template you had in your amplification reaction. The more starting material you have, the earlier the cycle number at which the fluorescence will rise above the threshold. The Mx3000P combines the capabilities of a microplate fluorescence reader with a PCR thermocycler so fluorescence levels can be read as the PCR reaction progresses. It uses a tungsten halogen white light bulb to provide the excitation light, and the range of excitation is 350-750nm. There is a single optical channels in the instrument, but along this optical channel there are two filter wheels, one with a set of 4 excitation filters and one with a set of 4 emission filters. This allows you to specifically excite and measure the fluorescent signal for up to 4 different dyes in one tube. The detection is done with a photomultiplier tube (PMT),. The detection range for the PMT is 350-700 nm. The thermal system uses a 96 well format, with a temperature range of 25-95 degrees Celsius, a thermal uniformity across the plate of +/- 0.25 degrees Celsius, and the ramping rate is dynamically controlled by the software up to a maximum of 2.5 degrees C/sec.

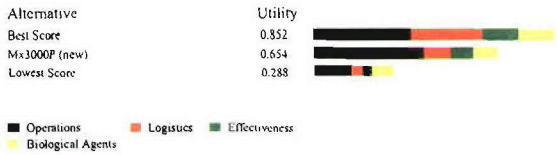
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Mx3000P ranked in the top third of all evaluated products for analytical laboratories and earned 76% of the utility points of the best score.

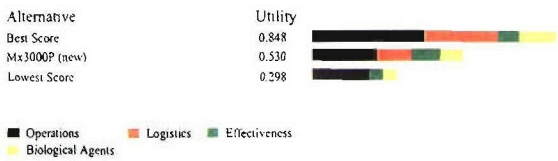
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Mx3000P ranked in the middle third of all evaluated products for diagnostic laboratories and earned 77% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

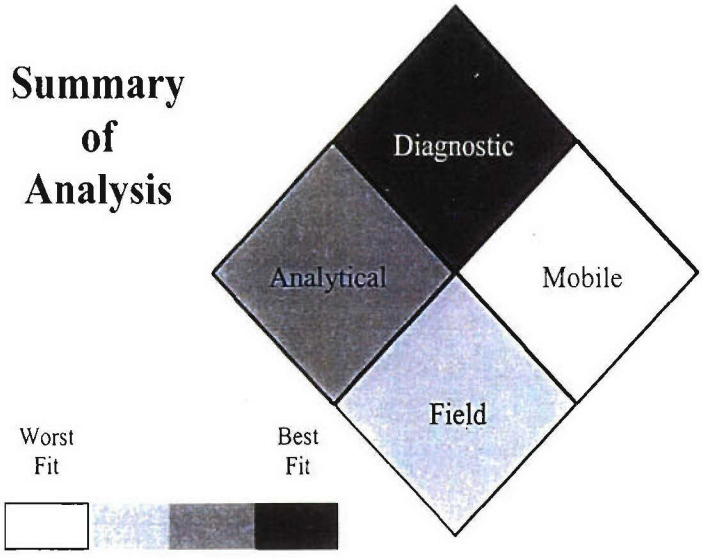
Mx3000P ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

Mx3000P ranked in the middle third of all evaluated products for field use and earned 70% of the utility points of the best score.

Summary of Analysis



Mx3000P Real Time PCR System
Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 min
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or approach is not amenable to automation

Training/Speed/Manpower:
- More than a day of training
- No set-up required
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumable or expendable needed
- Never needs service
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5-25 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Can view results "in real time"
- A single centrifugation step
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be frozen
- Device or system has peak performance at normal relative humidity conditions only

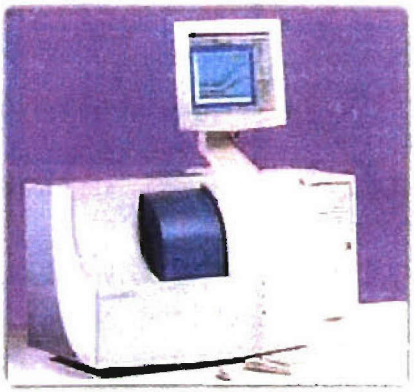
Cost: $ variable/sample
$24,995/device or system

Stratagene Inc.
11011 North Torrey Pines Rd.
La Jolla, CA 92037
www.Mx3000P.com

Point of Contact: Mike Metzler,
Al Grafsky, or Owen Hardy
(800) 894-1304 x 2
(858) 535-0034 fax
qpcrsystemssupport@stratagene.com

Mx4000 Multiplex Quantitative PCR System

by Stratagene Inc.



Description: The Mx4000 is a system for performing real-time quantitative PCR (QPCR). This technique allows researchers to quickly and easily quantify nucleic acids for studying gene expression, mutational analysis, disease state, gene dosage, and pathogen detection. QPCR measures PCR product accumulation during the exponential phase of the reaction and before amplification becomes vulnerable to limiting reagents and cycling variability. Fluorescent QPCR data provides accurate information on initial starting copy number. Using QPCR, amplification and detection are combined in a single step and in a single closed tube. This eliminates the need for numerous post-PCR manual steps, and reduces the possibility of introducing variability or laboratory contamination.

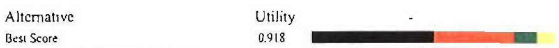
Able to Detect the Following Organisms/Toxins
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (4)
Brucella species (4)
Orthopox virus (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The Mx4000 can be used to detect and quantify the amount of a specific sequence DNA or RNA present as starting template prior to a PCR amplification reaction. This is done using a technique known as real-time quantitative PCR. This technology is based on the measurement of the fluorescence of either a double stranded DNA binding dye such as SYBR Green or a fluorescent dye-bound probe based system like Taqman, Molecular Beacons, or Scorpions Probes. For any of these systems, the amount of fluorescence will increase as the amount of amplified PCR product increases. Based on the cycle number in the PCR reaction where your fluorescence rises above a threshold of background fluorescence (the threshold cycle, or Ct) you can calculate how much starting template you had in your amplification reaction. The more starting material you have, the earlier the cycle number at which the fluorescence will rise above the threshold. The Mx4000 combines the capabilities of a microplate fluorescence reader with a PCR thermocycler so fluorescence levels can be read as the PCR reaction progresses. It uses a tungsten halogen white light bulb to provide the excitation light, and the range of excitation is 350-750nm. There are four optical channels in the instrument, each with its own set of excitation and emission filters to specifically excite and measure the fluorescent signal for up to 4 different dyes in one tube. The detection is done with four photomultiplier tubes (PMTs), one for each optical channel. The detection range for the PMTs is 350-830 nm. The thermal system uses a 96 well format, with a temperature range of 25-99 degrees Celsius, a thermal uniformity across the plate of +/- 0.25 degrees Celsius, and an adjustable ramping rate from 0.1 to 2.2 C/sec.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Mx 4000 Muluplex PCR Sys. (update)	0.711
Lowest Score	0.101

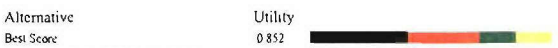


Preference Set = Analytical Laboratory

Mx4000 Multiplex Quantitative PCR System ranked in the top third of all evaluated products for analytical laboratories and earned 77% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Mx 4000 Multiplex PCR Sys. (update)	0.635
Lowest Score	0.288



Preference Set = Diagnostic Laboratory

Mx4000 Multiplex Quantitative PCR System ranked in the middle third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.

Mobile Laboratory Ranking

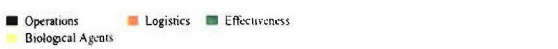
Alternative	Utility
Best Score	0.848
Mx 4000 Multiplex PCR Sys. (update)	0.451
Lowest Score	0.298

Preference Set = Mobile Laboratory

Mx4000 Multiplex Quantitative PCR System ranked in the bottom third of all evaluated products for mobile laboratories and earned 53% of the utility points of the best score.

Field Use Ranking

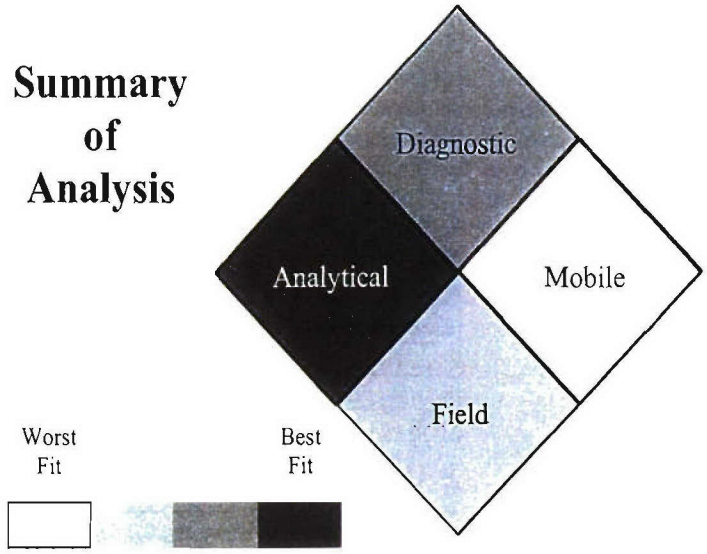
Alternative	Utility
Best Score	0.864
Mx 4000 Multiplex PCR Sys. (update)	0.559
Lowest Score	0.302



Preference Set = Field Use

Mx4000 Multiplex Quantitative PCR System ranked in the middle third of all evaluated products for field use and earned 65% of the utility points of the best score.

Summary of Analysis



Mx4000 Multiplex Quantitative PCR System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 96 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- More than a day of training
- No set-up required
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation step
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be frozen
- Performance of the device or system has a peak performance at normal relative humidity conditions only

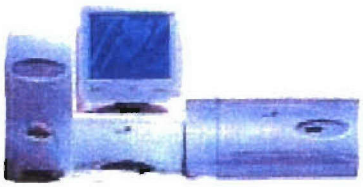
Cost: $variable/sample
$59,995.00/system or device

Stratagene Inc.
11011 North Torrey Pines Rd.
La Jolla, CA 92037
www.Mx3000P.com

Point of Contact: Mike Metzler
(800) 894-1304 ext. 15434
fax. (858) 535-0034
tech_services@stratagene.com

NanoChip Molecular Biology Workstation

by Nanogen, Inc.



Description: The NanoChip Molecular Biology Workstation is an automated multi-purpose instrument that facilitates detection of known sequences, such as in the analysis of Single Nucleotide Polymorphisms (SNPs) and Short Tandem Repeats (STRs) using the NanoChip Electronic Microarray. The unique, open-architecture design permits researchers to define, select and build their own test panels or select from predefined.

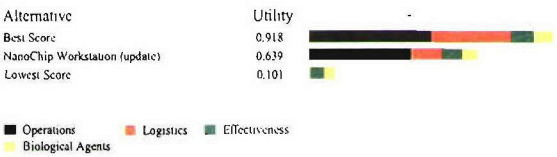
Able to Detect the Following Organisms:
Bacillus anthracis (1)
E. coli 0157:H7 (1)
Yersinia pestis (1)
Orthopox virus (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Our fully integrated NanoChip System consists of three major subsystems: (1) the NanoChip Loader for loading samples on one to four NanoChip Cartridges, (2) the NanoChip Reader, a highly sensitive, laser-based fluorescence scanner for detection of assay results and (3) computer hardware and software which automates import, analysis and export of sample information making data analysis simple. The NanoChip System is based on electronic addressing which involves placing charged molecules at specific test sites on a NanoChip microarray. Electronic addressing allows on-chip hybridization to occur within seconds compared to several hours in passive hybridization. In addition, DNA target molecules are electronically concentrated at the array sites, exceeding ca 1000 times the concentration in the bulk of solution. When a biotinylated sample solution is introduced onto the array, the negatively charged sample rapidly moves to the selected positively charged sites, where it is concentrated and bound to the streptavidin in the permeation layer. The array is then washed and another sample can be added. Site by site, row by row, an array of samples are assembled on the array. Such user-definable microchip arrays allow the customer to respond quickly to the ever evolving list of genes to be tested. The customer may analyze multiple genes from a single test site (representing one sample) or from multiple test sites (representing different samples). The customer also has the ability to electronically address multiplexed amplicons to a single test site.

To date, we have developed two Analyte Specific Reagents (ASRs) - Factor V (Leiden) and Cystic Fibrosis and we offer research application notes for determining the following genes: Factor (II) prothrombin (coronary disease), Factor V/II multiplex(cardiovascular disease); MTHFR (cardiac function); hereditary hemochromatosis (venous thrombotic disease). This same platform has been used for development and testing of amplified DNA samples of biological warfare agents.

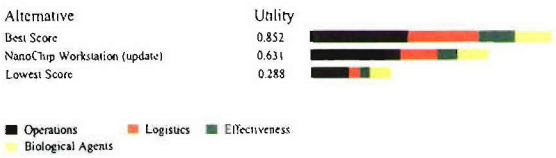
Analytical Laboratory Ranking



Preference Set – Analytical Laboratory

NanoChip Molecular Biology Workstation ranked in the middle third of all evaluated products for analytical laboratories and earned 70% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

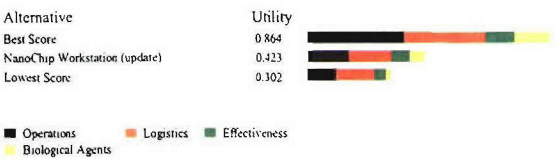
NanoChip Molecular Biology Workstation ranked in the middle third of all evaluated products for diagnostic laboratories and earned 74% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set – Mobile Laboratory

NanoChip Molecular Biology Workstation ranked in the bottom third of all evaluated products for mobile laboratories and earned 51% of the utility points of the best score.

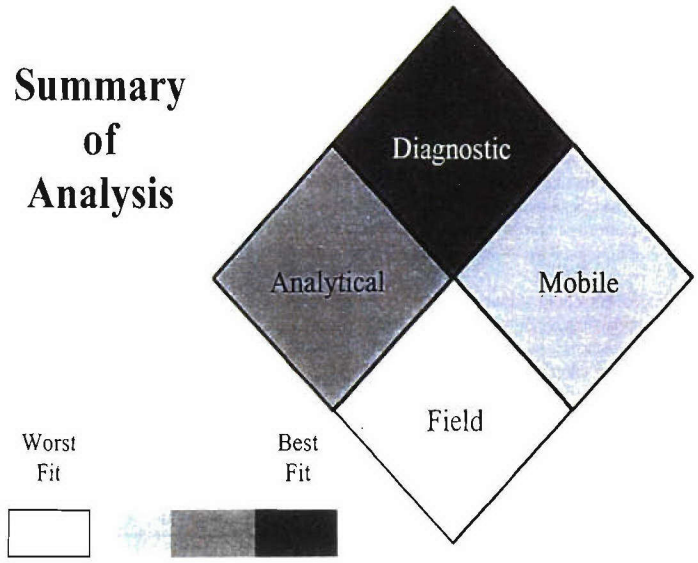
Field Use Ranking



Preference Set = Field Use

NanoChip Molecular Biology Workstation ranked in the bottom third of all evaluated products for field use and earned 49% of the utility points of the best score.

Summary of Analysis



NanoChip Molecular Biology Workstation Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 50 and 60 minutes
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- More often than every 6 months service required
- Expected life is greater than 10 years
- 10-20 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

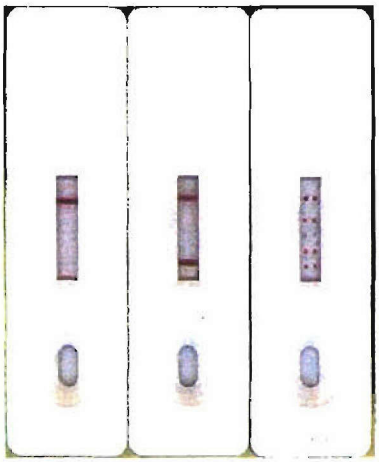
Cost: $Unknown/sample
$165,000.00/system or device

Nanogen, Inc
10398 Pacific Center Court
San Diego, CA 92121
www.nanogen.com

Point of Contact: Sales Department
(877) nanogen

NIDS (Nano-Intelligent Detection System) Assay

by ANP Technologies, Inc.



Description: Handheld immunochromatographic assays offer many unique advantages over their bulky instrument-based counterparts: they are compact, easy to use, and have no power source requirements. Simple sample preparation and data interpretation have made them a preferred tool over gene-based assays for rapid field detection and point-of-care applications such as home pregnancy tests and cardiac marker detection. Due to the difficulty in controlling protein binding events at the nanoscale, protein-based assays often exhibit low sensitivity and unacceptably high false positive responses. ANP Tech's team has recently developed dramatically improved handheld assay and microarray devices that can reliably detect the presence of biological agents at extremely low concentrations.

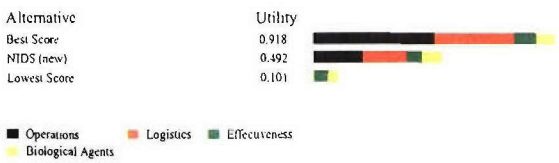
The new devices have been engineered with ANP Tech's unique nanomanipulation technology. This approach enhances assay sensitivity up to 100 fold, while virtually eliminating false positive readings verses analogous conventional protein-based assays. Our products significantly o utperformed others at the DoD-sponsored Joint Field Trial 6. In addition, our technology allows the use of very small sample volumes, with no need for elaborate preparatory steps. Our system has been successfully demonstrated for a variety of biological threat agents, including B. anthracis bacterial spores, Y. pestis bacteria, smallpox virus, as well as ricin and botulinum toxins. ANP Tech's new protein microarray design also allows for the simultaneous detection of multiple biological a gents, and has great promise for proteomics-related applications, such as high throughput protein target discovery and drug lead screening.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (2)
Francisella tularensis (1)
Yersinia pestis (1)
Coxiella burnetti (1)
Brucella species (1)
Smallpox virus (1)
MS-2 bacteriophage (1)
Botulinum toxin A (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The key to high sensitivity and low false positive rate is the nano-manipulation techniques that essentially align the antibodies so that the biological sensing region (Fab) is virtually always available for interactions with the target molecule. This is accomplished through the reaction of a functionalized polymer additive with the antibody prior to its incorporation in the assay. The polymer additives orient the antibodies to their optimal sensing configuration and also interact with one another to form an ordered array of antibodies available for detection of target molecules. The polymers are designed for optimal interactions with specific antibodies and each other through varying the type and amount of surface functional groups. This nano-manipulation of the antibodies reduces the false positive rate by eliminating non-specific binding interaction, and increases the detection sensitivity of the assay through by orienting the antibodies to their optimal sensing configuration.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

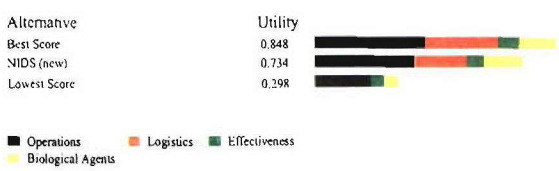
NIDS ranked in the bottom third of all evaluated products for analytical laboratories and earned 54% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

NIDS ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 67% of the utility points of the best score.

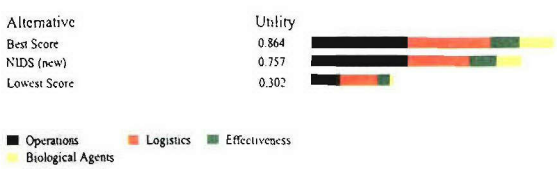
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

NIDS ranked in the top third of all evaluated products for mobile laboratories and earned 87% of the utility points of the best score.

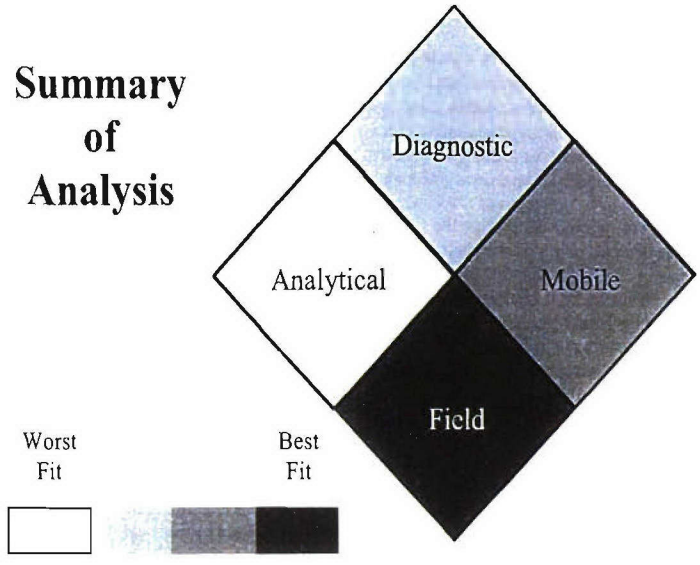
Field Use Ranking



Preference Set = Field Use

NIDS ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

Summary of Analysis



Nano-Intelligent Detection System

Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device has no electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Never needs service
- Expected life measure (not applicable)
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- The influence on performance of the device or system by relative humidity is unknown

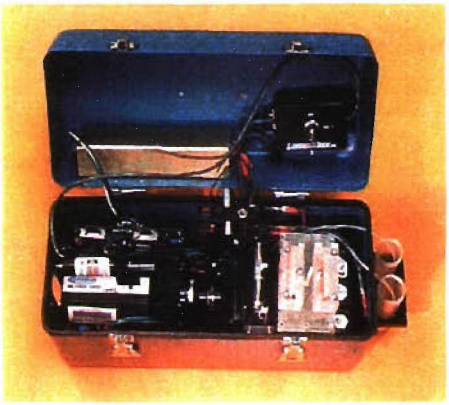
Cost: To Be Determined

ANP Technologies, Inc.
824 Interchange Blvd
Newark, DE 19711
www.anptinc.com

Point of Contact: Robert Daniel
302-283-1730
302-283-1733 fax
robert@anptinc.com

NRL Array Biosensor

by Naval Research Laboratory



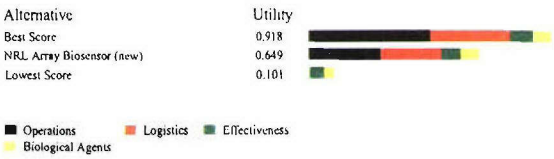
Description: The array biosensor is an automated, portable detection device for simultaneous analysis of multiple samples for multiple analytes. It has progressed through a series of prototypes to obtain a reliable, small system to which a user can add six samples, with minimal, if any, sample preparation, and test for a variable number of targets. The current system weighs less than 6 kg and is operated using a laptop computer. The user places two reservoir modules in the system, one containing up to six samples and the other containing up to six cocktails of tracer reagents, and starts the assay. The fluidic system automatically runs the samples over the waveguide, exposes the waveguide to tracer, and washes out excess tracer. Image acquisition and data analysis are still performed offline, but the program to determine the boundaries of the spots and background controls and to calculate mean increase in fluorescence over the background is semi-automated. Applications explored to date include detection of infectious diseases and toxins in clinical fluids, food (liquids and homogenates), drinking water and environmental samples. In most cases, toxins can be detected at 0.1-1 ng/mL and bacteria at ~1000 cfu/mL without any target preconcentration. Assays for multiple targets are generally performed in 12 minutes; extending the time increases the sensitivity.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli O157:H7 (1)
Francisella tularensis (1)
Vibrio cholera (1)
Yersinia pestis (1)
Brucella species (1)
Botulinum toxin A &B (1)
SEB (1)
Ricin (1)
Aflatoxin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The biochemical component of the multi-analyte biosensor consists of a patterned array of biological recognition elements ("capture" antibodies, oligosaccharides, antibiotics, other generic or specific receptors) immobilized on the surface of a planar waveguide. A fluorescence assay is performed on the patterned surface, yielding an array of fluorescent spots, the loci of which are used to identify what target is present. Signal transduction is accomplished by means of a diode laser for fluorescence excitation and a CCD camera for image capture. Data analysis software has been developed to quantify the fluorescent signals in each spot. The assays are fast, sensitive, and specific; up to 32 immunoassays have been conducted simultaneously on 6 independent samples. NRL has demonstrated the ability to detect proteins, toxins, bacteria, and viruses in a variety of physiological , food, and environmental matrices

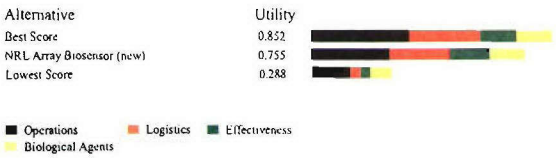
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

NRL Array Biosensor ranked in the middle third of all evaluated products for analytical laboratories and earned 71% of the utility points of the best score.

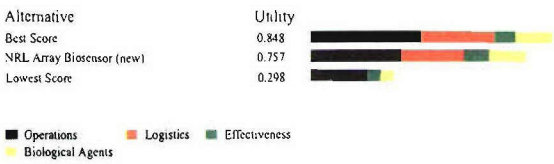
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

NRL Array Biosensor ranked in the top third of all evaluated products for diagnostic laboratories and earned 89% of the utility points of the best score.

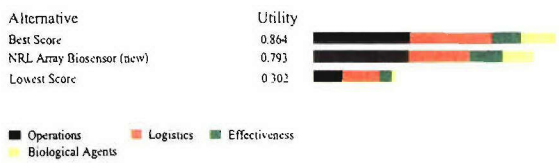
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

NRL Array Biosensor ranked in the top third of all evaluated products for mobile laboratories and earned 89% of the utility points of the best score.

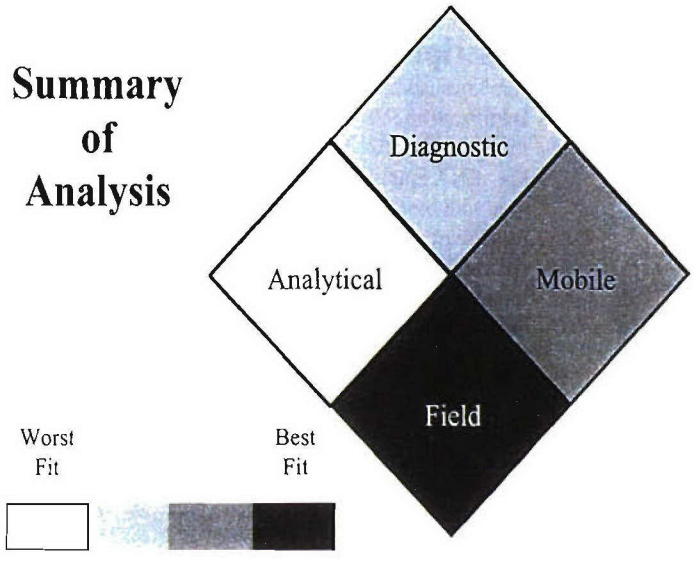
Field Use Ranking



Preference Set = Field Use

NRL Array Biosensor ranked in the top third of all evaluated products for field use and earned 92% of the utility points of the best score.

Summary of Analysis



NRL Array Biosensor
Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within three or more calendar years
- A few systems or devices exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 20 min or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- Very brief training
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 2 solution or buffer used
- 5 or more components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Never needs service
- Expected life measure not applicable
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 5-25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Ability to view results "in real time" depends upon application
- No centrifugation steps
- No shaking or vortexing steps
- System may be able to interpret raw data or call a positive through internal software in the future
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $ unknown/sample
$10,000/device or system

Naval Research Laboratory
Center for Bio/Molecular Science & Engineering, Code 6900
Washington, DC 20375-5348
cbmse.nrl.navy.mil

Point of Contact: Frances Ligler
202-404-6002
202-404-8897 fax
fligler@cbmse.nrl.navy.mil

NucliSens EasyQ System

by bioMerieux

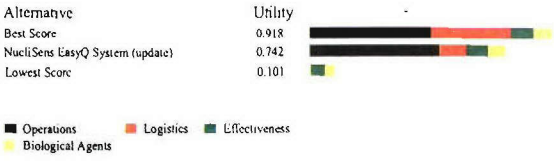
Description: The NucliSens EasyQ System combines isothermal (41C) nucleic acid sequence-based amplification (NASBA) and molecular beacon detection for Real-Time RNA assays using the NucliSens Basic Kit. RNA amplification assays are developed by the user with bioMerieux support. The system is designed for ease of use in low or large volume molecular testing laboratories. Amplification time is generally 60 minutes, with total time to result for amplification and detection of less than 2 hours for 48 samples. Commercially have done studies to link with automated and manual sample prep.

Technology: The NucliSens EasyQ System combines nucleic acid sequenced-based amplification (NASBA) and real-time molecular beacon detection. The system is designed for ease of use and is equally suited to large or small volume molecular testing. Real-time NASBA amplification with molecular beacon detection equals rapid reaction time and often total time to result for amplification and detection in less than two hours and in some cases less than 15 minutes for 48 samples. NASBA technology is an isothermal process that uses three enzymes (AMV-RT, RNase H and T7 RNA polymerase) and target specific oligonucleotides. The reaction run at 41C, generating single stranded RNA as an end product. Windows based open software generates results, melting curve data and run performance information. The system is compact with a footprint of 16.5 x 16.5 in. combined with a small incubator and dedicated computer and centrifuge.

Able to Detect the Following Organisms:
VEE virus (1)
Dengue fever virus (2)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

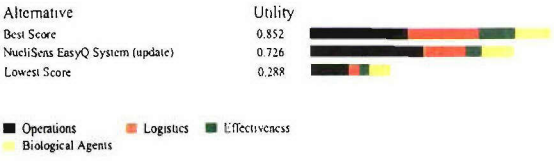
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

NucliSens EasyQ System ranked in the top third of all evaluated products for analytical laboratories and earned 81% of the utility points of the best score.

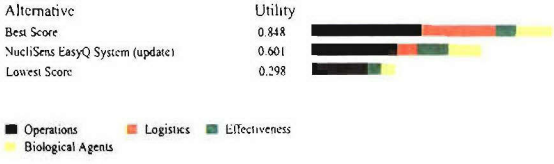
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

NucliSens EasyQ System ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

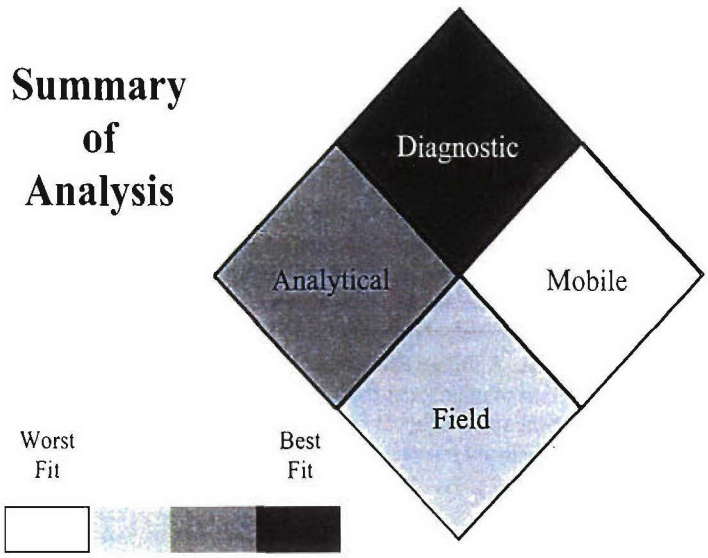
NucliSens EasyQ System ranked in the middle third of all evaluated products for mobile laboratories and earned 71% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

NucliSens EasyQ System ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.

Summary of Analysis



NucliSens EasyQ System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 50 and 60 minutes
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 5 or more components
- Monthly maintenance required

Maintenance:
- 0-1 consumable or expendable needed
- Less than once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation step
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Device or system has peak performance at normal relative humidity conditions only

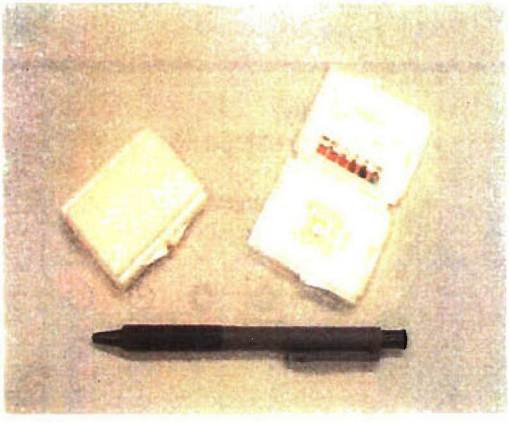
Cost: Approx. $10.00/sample
$38,000.00/system or device

bioMerieux
100 Rodolphe St.
Durham, NC 27712
www.biomerieux-usa.com

Point of Contact: Lynell Grosso
(919) 620-2094
fax. (919) 620-7019
lynell.grosso@na.biomerieux.com

Optical Immuno-assay

by Thermobiostar



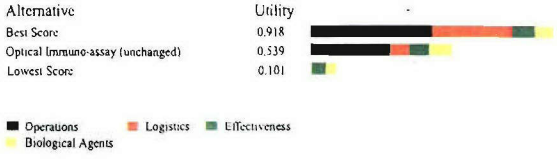
Description: Thermobiostar currently produces a small, rapid (15minute), easy to operate immuno-based detection assay. These assays are based on the change in refractive index of a small silicon based wafer due to deposition of enzymatic product following binding of a secondary, detection antibody to the target organism which has been captured by specific detection antibody adhered to the wafer. This technology, which currently exists for detection of clinically relevant infectious agents, such as streptococcus and influenza, is being adapted through a CRADA with the Naval Research Laboratory and modified for the rapid detection of environmental and potential bioterrorism agents. The assay is rapid, extremely sensitive (equivalent or better than ELISA) and is capable of quantitative detection. A further advantage of the assay is the capability to incorporate detection of multiple agents (10 or more) onto a single chip, greatly increasing the speed of agent detection. The assay, in its current configuration for clinically relevant infectious agents, is being used in many clinical laboratories and physician's offices around the country.

Technology: The assay is predicated on the change in refractive index associated with the formation of a thin–film created by deposition of enzymatic product resulting from reaction of enzyme, attached to detection antibody antibody, with its substrate. The operation of the assay is summarized by reacting the target antigen to the silicon wafer which has been derivatized with specific capture antibody. The antigen bound wafer is then further reacted with secondary, detection antibody conjugated with enzymatic probe. Visualization is conducted by further reaction of the wafer with substrate to form a thin-film, yielding a change in color of the chip which is readily detected by eye. The color changes from its normal red color to various shades of blue and ultimately white, depending on the concentration of antigen in the sample.

Able to Detect the Following Organism/Toxins:
Bacillus anthracis (1)
Botulinum toxin A (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

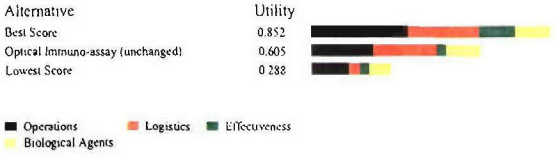
Analytical Laboratory Ranking



Preference Set – Analytical Laboratory

Optical Immuno-assay ranked in the middle third of all evaluated products for analytical laboratories and earned 59% of the utility points of the best score.

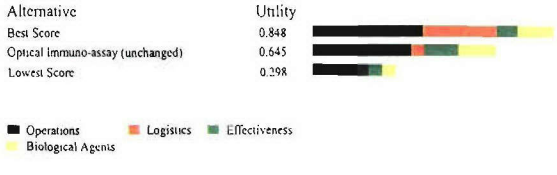
Diagnostic Laboratory Ranking



Preference Set – Diagnostic Laboratory

Optical Immuno-assay ranked in the middle third of all evaluated products for diagnostic laboratories and earned 71% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set – Mobile Laboratory

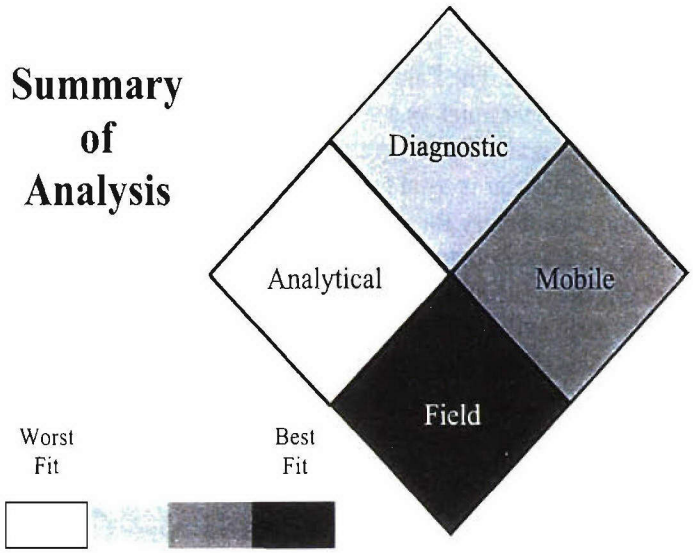
Optical Immuno-assay ranked in the top third of all evaluated products for mobile laboratories and earned 76% of the utility points of the best score.

Field Use Ranking

Preference Set – Field Use

Optical Immuno-assay ranked in the top third of all evaluated products for field use and earned 90% of the utility points of the best score.

Summary of Analysis



Optical Immuno-assay Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- No electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 20 and 30 minutes
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 2 solutions or buffers used
- 4 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 6 months and 1 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 25°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: Approx. 10.00/sample
Approx. $10.00 /system or device

Thermobiostar
6655 Lookout Road
Boulder, CO 80301
www.thermobiostar.com

Point of Contact: John Dorson
(800) 637-3717
fax. (303) 581-6405
j_Dorson@thermobiostar.com

Palm-Cycler

by Corbett Research

Description: The Palm-Cycler is designed to regulate temperatures in a small metal block based on user programs for temperature and cycling times. The Palm-Cycler is used to facilitate the enzymatic reactions necessary for many detection methods. It does not directly detect anything itself. There are a wide array of sequencing , DNA amplification, Real-Time and iso thermal reaction assays that can be used on the Palm-Cycler.

No Formal Detection Assay Available

Technology: Overall, the Palm-Cycler is a very simple system to operate. The temperature can be regulated from 4°C-99°C in a 96 x 0.2ml, 384 x 0.1ml pr 60 x 0.5ml block. The system utilizes a heated lid to prevent condensation and is controlled by an HP Journada, a pocket PC device.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Palm-Cycler PCR (update)	0.633
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

Palm-Cycler ranked in the middle third of all evaluated products for analytical laboratories and earned 69% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Palm-Cycler PCR (update)	0.645
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

Palm-Cycler ranked in the middle third of all evaluated products for diagnostic laboratories and earned 76% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Palm-Cycler PCR (update)	0.581
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

Palm-Cycler ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.

Field Use Ranking

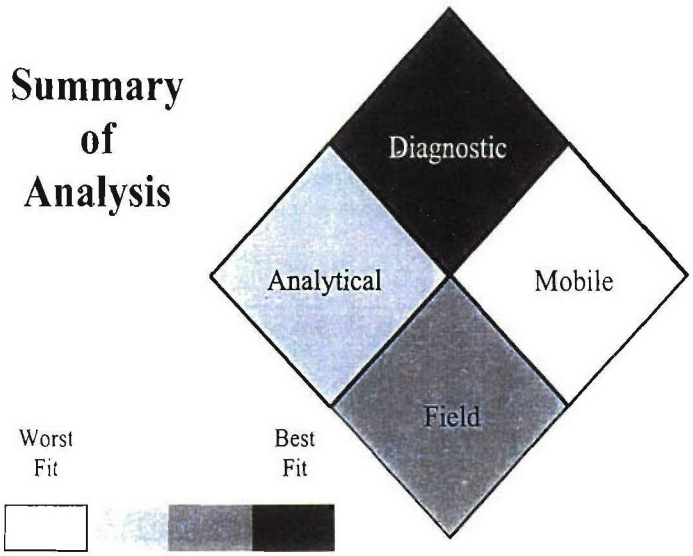
Alternative	Utility
Best Score	0.864
Palm-Cycler PCR (update)	0.644
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

Palm-Cycler ranked in the middle third of all evaluated products for field use and earned 75% of the utility points of the best score.

Summary of Analysis



Palm-Cycler Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Detection performed in greater than 60 minutes
- 96 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 1 component
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Less than once a year service required
- Expected life is 5-10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System is never able to interpret raw data or call a positive through internal software
- System cannot detect multiple biological agents or toxins detection within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 4°C, and stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $NA/sample
$4,995/system or device

Corbett Research
1/14 Hilly Street
Mortlake, NSW 2137 Australia
www.corbettresearch.com

Point of Contact: John Corbett
011-612-973-613-20
fax. 011-612-973-613-64
john@corbettesearch.com

PathAlert Detection System

by Invitrogen

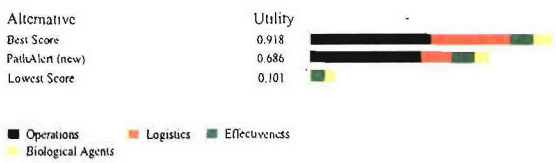
Description: The PathAlert Detection System provides accurate and highly sensitive identification of infectious agents. Four multiplex, quantitative PCR kits provide specific detection of pathogens including *Bacillus anthracis* (Anthrax), *Yersinia pestis* (Plague), *Francisella tularensis* (Tularemia), or Orthopox (Smallpox). A complete set of controls provides functional validation of each PCR reaction—to ensure accuracy of results.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (4)
Orthopox virus (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: PathAlert™ Detection Kits (Figure 1) contain a unique PCR SuperMix. Each PathAlert™ PCR SuperMix is a 2Xconcentrated, ready-to-use reaction cocktail containing all components, except sample template, for the amplification of DNA using the polymerase chain reaction The PathAlert SuperMix formulation delivers exceptional sensitivity, precision, and accuracy in the quantification of target sequences, with a linear response over a wide range of target concentrations. The PathAlert Detection System eliminates human error that can arise from incorrect assembly of multiple reagents or cross-contamination of individual reagents. Technicians can rapidly and easily add the SuperMix to prepared samples

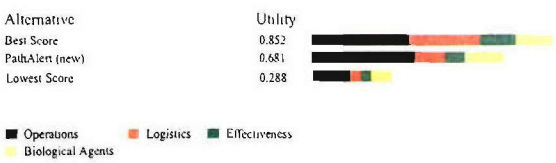
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

PathAlert ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set – Diagnostic Laboratory

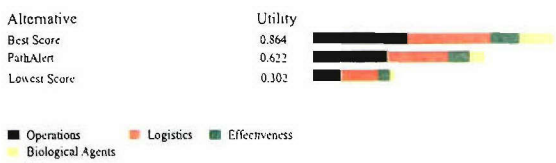
PathAlert ranked in the middle third of all evaluated products for diagnostic laboratories and earned 80% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set – Mobile Laboratory

PathAlert ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.

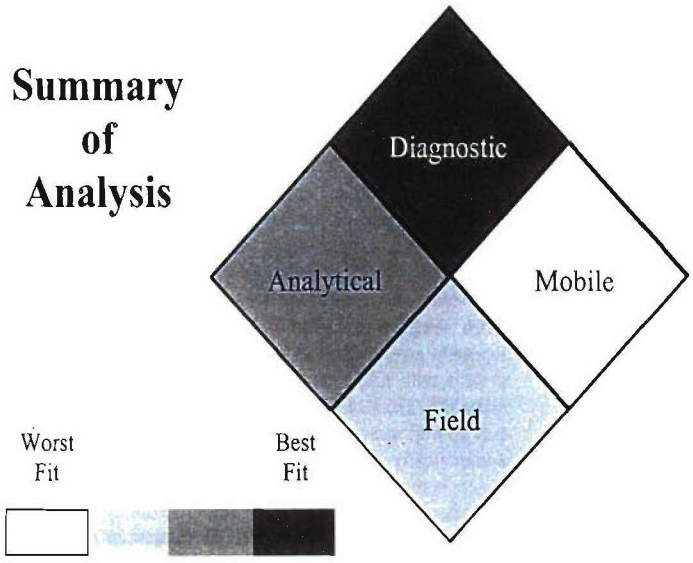
Field Use Ranking



Preference Set = Field Use

PathAlert ranked in the middle third of all evaluated products for field use and earned 72% of the utility points of the best score.

Summary of Analysis



PathAlert Detection System

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 min
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 5 or more components
- No cleaning required

Maintenance:
- 3 consumable or expendable needed
- Needs service once a year
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5-25 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, and capable of detecting two or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $16.50/sample
Approximately $30,000-35,000 /device or system

Invitrogen
7335 Executive Way
Frederick, MD 21704
www.invitrogen.com/pathogenresearch

Point of Contact: Bill Folkerts
240-379-4209
Willem.Folkerts@invitrogen.com

Portable NanoChip Molecular Biology Workstation

by Nanogen, Inc.

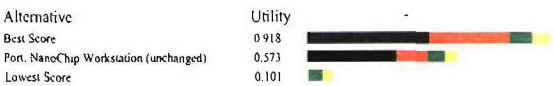
Able to Detect the Following Organisms:
Bacillus anthracis (1)
E. coli 0157:H7 (1)
Yersinia pestis (1)
Orthopox virus (1)
SEB (1)

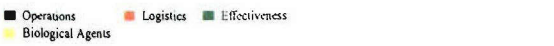
(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Description: The Portable NanoChip Molecular Biology Workstation is a miniaturized automated instrument that facilitates detection of known DNA sequences, primarily developed for the of biological warfare agents using the 400-site NanoChip Electronic Microarray. The unique, open-architecture design permits users to easily develop new assays for bacterial or viral identification as well as other genetic analysis applications. The Portable NanoChip System uses CMOS 400-site microarray embedded into a cartridge for electronic addressing of the DNA samples or probes onto the array. The fluorescent reporters are attached passively or actively and an optical system with CCD camera measures fluorescence at each array site. The samples are simply pipetted through a sample cup as well as some of the reagents needed in the tests and automatically pumped onto the microarray chip. Buffer and waste bottles are housed in the instrument. The software provides fully automated fluidic control, electronic addressing on the array as well as fluorescent image data display and interpretation.

Technology: Nanogen's NanoChip technology is used in the instrument which is based on electronic addressing of charged molecules at specific test sites on the NanoChip microarray. Electronic addressing allows on-chip hybridization to occur within seconds compared to several hours in passive hybridization. In addition, DNA target molecules are electronically concentrated at the array sites, exceeding ca 1000 times the concentration in the bulk of solution. When a biotinylated sample or probe is introduced onto the array, the negatively charged molecules rapidly move to the selected positively charged sites, where it is concentrated and bound to the streptavidin in the permeation layer. The array is then washed and another sample can be added. Site by site, row by row, an array of samples are assembled on the array and fluorescence detected. The platform allows both electronic and thermal stringency assays to be developed which assure single base pair recognition. The customer may analyze multiple genes from a single test site (representing one sample) or from multiple test sites (representing different samples). The customer also has the ability to electronically address multiplexed amplicons to a single test site. DNA samples amplified by PCR, or strand displacement amplification (SDA) can be used in the analysis. In addition, Nanogen developed an on-chip SDA DNA amplification method for the detection of geological warfare agents. This method allows multiplexed amplification on the chip as well as detection of amplified products.

Analytical Laboratory Ranking

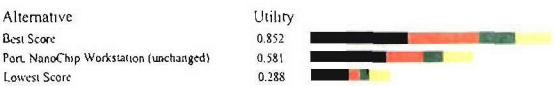




Preference Set = Analytical Laboratory

Portable NanoChip Molecular Biology Workstation ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.

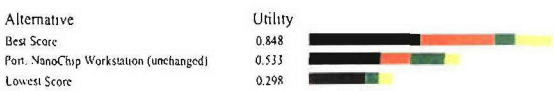
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Portable NanoChip Molecular Biology Workstation ranked in the middle third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.

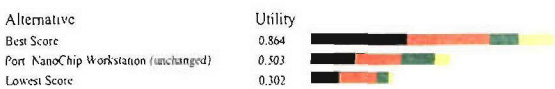
Mobile Laboratory Ranking

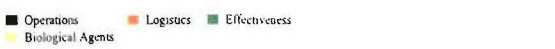


Preference Set – Mobile Laboratory

Portable NanoChip Molecular Biology Workstation ranked in the middle third of all evaluated products for mobile laboratories and earned 63% of the utility points of the best score.

Field Use Ranking

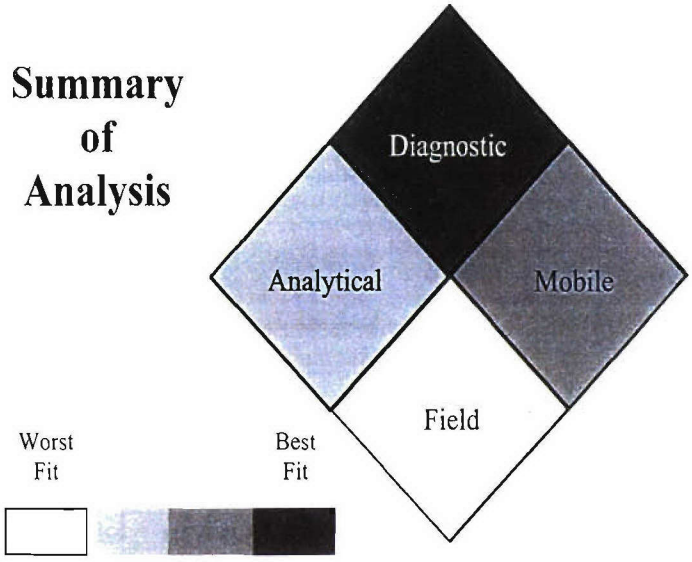




Preference Set = Field Use

Portable NanoChip Molecular Biology Workstation ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.

Summary of Analysis



Portable NanoChip Molecular Biology Workstation Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

System requirements:
- System or device uses batteries or 110V requirement
- The system or device does require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 40 and 50 minutes
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- 5-10 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- More often than every 6 months service required
- Expected life is greater than 10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

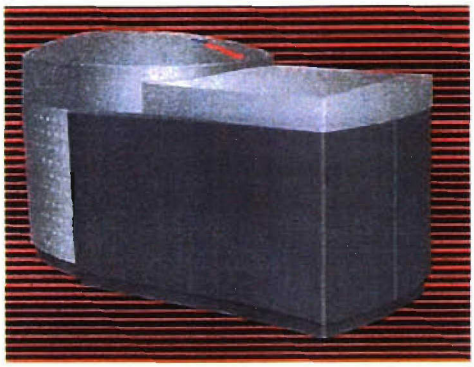
Cost: $Unknown/sample
$Unknown/system or device

Nanogen, Inc.
10398 Pacific Center Court
San Diego, CA 92121
www.nanogen.com

Point of Contact: Sales Department
(877) nanogen

Sector PR 100

by Meso-Scale Discoveries



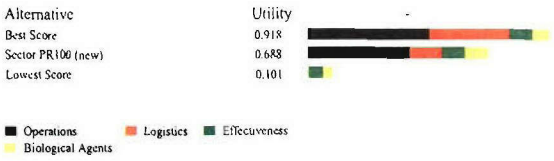
Description: The Sector PR 100 is an electrochemiluminesence (ECL) based system using assay reagents that are directly immobilized on the electrode used to induce ECL. The carbon-based electrodes are in the form of standard microtiter plates with 96 wells per plate. The centerpiece of this system is an array of photodiodes which enable rapid, highly sensitive measurements. The system was originally designed for use by the pharmaceutical industry in support of their assay development efforts. On top of superior detection capabilities across the spectrum of potential bioagents (viruses, bacteria and toxins,) the MSD instrument is easy to use and capable of providing results in 30 minutes or less for over 96 tests. The Sector PR 100 is perfectly suited for the needs of either a central lab demanding highly sensitive measurements in a rapid pace for a large volume of samples or a solider out in the field.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (2)
E. coli O157:H7 (1)
Francisella tularensis (1)
Yersinia pestis (2)
VEE virus (2)
Botulinum toxin A (1)
SEB (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Electrochemiluminescence (ECL) is a well-developed, commercial technology for the detection and study of biomolecular interactions and function. ECL-based assays employ labels that emit light when electrochemically oxidized or reduced under appropriate chemical conditions. The existence of small, stable and highly efficient ECL labels makes the technique robust, sensitive and easy to implement. ECL detection is already widely used in the military for detection of biological agents. We have adapted the technology to allow ECL assays to be carried out on inexpensive disposable electrodes. Our systems are currently being evaluated at the Edgewood Chemical and Biological Center and USAMRIID. Assays are carried out on proprietary Multi-ArrayTM plates having integrated electrodes that act as both a capture surface and an energy source for electrochemiluminescence excitation. The approach allows us to achieve the excellent performance characteristics of ECL based measurements using simple, low-maintenance instrumentation. Assay designed for the Sector PR 100 are formatted on 96-well Multi-Array plates. The plates are manufactured using well-established scalable techniques such as screen-printing that allow for high volume manufacturing at low cost. These assays are capable of highly sensitive detection with broad dynamic ranges. The Sector PR 100 can read a 96-well plate in a little under 2 mintues.

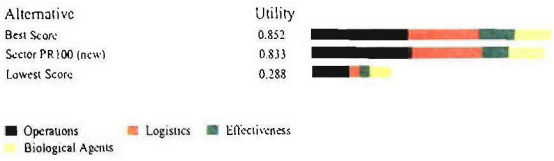
Analytical Laboratory Ranking



Preference Set - Analytical Laboratory

Sector PR100 ranked in the top third of all evaluated products for analytical laboratories and earned 75% of the utility points of the best score.

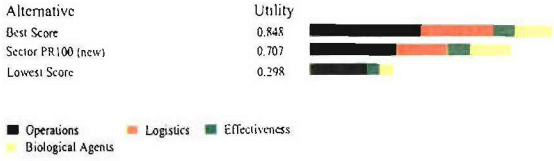
Diagnostic Laboratory Ranking



Preference Set - Diagnostic Laboratory

Sector PR100 ranked in the top third of all evaluated products for diagnostic laboratories and earned 98% of the utility points of the best score.

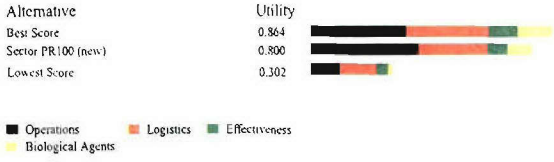
Mobile Laboratory Ranking



Preference Set - Mobile Laboratory

Sector PR100 ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.

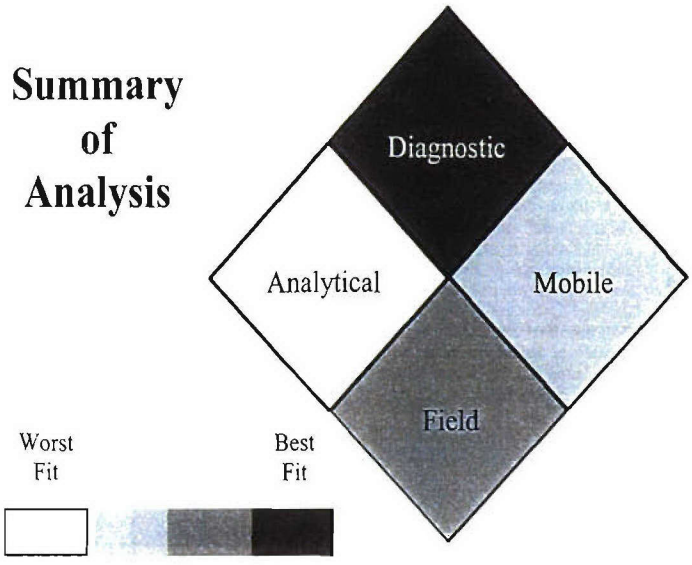
Field Use Ranking



Preference Set - Field Use

Sector PR100 ranked in the top third of all evaluated products for field use and earned 93% of the utility points of the best score.

Summary of Analysis



Sector PR 100
Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device uses batteries
- The system or device does not require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in less than 20 min
- 96 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 1 components
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Never needs service
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5-25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- A single shaking or vortexing step
- System can interpret raw data or call a positive through internal software
- Not capable of detecting multiple agents or toxins within the same well
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at 25°C to 37°C
- Performance of the device or system is not influenced by relative humidity

Cost: <$4.00/assay
$25,000/device or system

Meso-Scale Discoveries
9238 Gaither
Gaithersburg, MD 20878
www.meso-scale.com

Point of Contact: Vit Vasista
(240) 631-2522 x4622
(240) 632-2219 fax
vvasista@meso-scale.com

PROFILE-1 ATP Luminescence System

by New Horizons Diagnostics Corp.

Description: New Horizon Diagnostics Corporation (NHD) manufactures a hand-held, generic detector for ATP in living systems with no specificity, battery operated (AC-DC), luminometer that is capable of determining the presence of viable low levels of bacteria and spores. The protocol incorporates a method for the removal of non-bacterial cells as well as potential interferents. The System provides Real-Time results; 5 minutes for bacterial detection and 20 minutes for spore detection. The PROFILE System detects only viable organisms and has the capability to quantitate bacterial levels. PROFILE has received FDA 510(k) for human use (bacteria in urine), field validated by USDA for bacterial detection on meat carcasses, field tested by WHO labs for water samples, and tested by DOD for detection of spores. More recently, DARPA funded studies have demonstrated the utility of the System to detect and identify as low as 100 *Bacillus anthracis* spores in less than 30 minutes. Identification can be made via utilization of specific bacteriophage lytic enzymes or antibodies The PROFILE is a field instrument that was incorporated in the original BIDS for air samples. There is also application for other environmental samples (powders, surfaces, etc.) water, food, as well as fuel oils. Detection limits are normally between 1000 and 100,000 cells, depending on the debris in the sample area, but the system can be adjusted to detect 100 or less cells The System has been incorporated in a Bio-Screen "Triage" system for First Responders As part of a "Layered" approach system, PROFILE received highest score for general detection in DOD study (ECBC-TR-171)

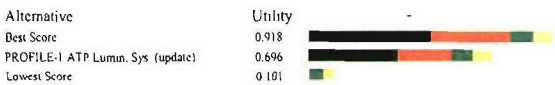
Able to Detect the Following Organisms:
Generic Bacterial/spore (3)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Luminescence is the emission of light that does not derive energy from the temperature of the emitting body. It is caused by chemical, biochemical, or physical changes of a material in a sample. Luminescence techniques utilize this phenomenon to measure the presence of an analyte in a sample that exhibits this characteristic. This typically is achieved by the reaction of the analyte with a substrate that produces light. Luciferin-Luciferase (L/L) luminescence techniques are used to measure the adenosine triphosphate (ATP) content (pg/ml) in samples containing either vegetative bacterial cells or spores. Evaluation for the presence of total bio-mass from both bacterial and non-bacterial sources of ATP is achieved by suspending the collected samples in phosphate buffered saline (PBS), transferring an aliquot of the PBS suspension into a Filtravette, adding bacterial releasing agent (BRA), then adding L/L. The sample then reacts with the L/L, and the resulting Relative Light Units (RLU) indicative of the total ATP content, are measured. Identical techniques are used to prepare the bacterial cells for analysis – with one additional step: a wash of the sample with somatic cell releasing agent (SRA) before adding BRA. The SRA wash is added to the Filtravette along with the sample and lyses all non-microbial (somatic & quenching) cells. These lysed cells are removed from the Filtravette via positive pressure, leaving the bacterial cells whole on the surface of the Filtravette.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
PROFILE-1 ATP Lumin. Sys. (update)	0.696
Lowest Score	0.101

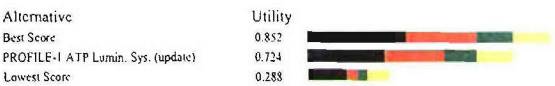


Preference Set – Analytical Laboratory

PROFILE-1 ATP Luminescence System ranked in the top third of all evaluated products for analytical laboratories and earned 76% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
PROFILE-1 ATP Lumin. Sys. (update)	0.724
Lowest Score	0.288

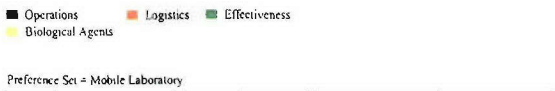


Preference Set – Diagnostic Laboratory

PROFILE-1 ATP Luminescence System ranked in the top third of all evaluated products for diagnostic laboratories and earned 85% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
PROFILE-1 ATP Lumin. Sys. (update)	0.746
Lowest Score	0.298



Preference Set – Mobile Laboratory

PROFILE-1 ATP Luminescence System ranked in the top third of all evaluated products for mobile laboratories and earned 88% of the utility points of the best score.

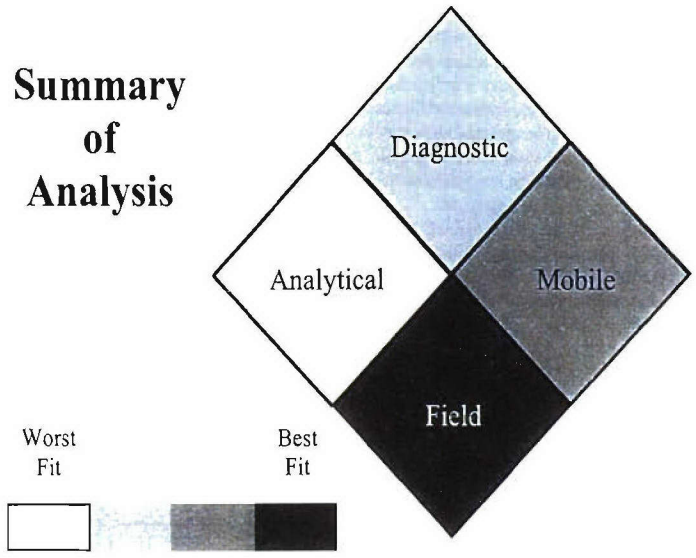
Field Use Ranking

Alternative	Utility
Best Score	0.864
PROFILE-1 ATP Lumin. Sys. (update)	0.822
Lowest Score	0.302

Preference Set – Field Use

PROFILE-1 ATP Luminescence System ranked in the top third of all evaluated products for field use and earned 95% of the utility points of the best score.

Summary of Analysis



PROFILE-1 ATP Luminescence System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- Very brief training
- Less than 5 min required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 3 solutions or buffers used
- 3 components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life is 5-10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System could be able to interpret raw data or call a positive through internal software in the future
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $4.00-8.00/sample
$4,000.00/system or device

New Horizons Diagnostic Corp.
9110 Red Branch Rd.
Columbia, MD 21045
www.NHDiag.com

Point of Contact: David Trudil
(410) 992-9357 ext. 222
fax. (410) 992-0328
NHDiag@aol.com

RAMP

by Response Biomedical Corp.

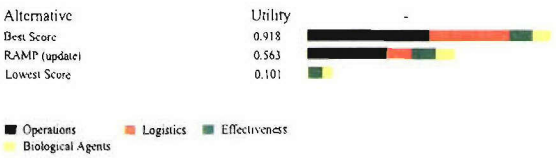
Description: RAMP is a rapid qualitative immunochromatographic system for the screening of environmental samples such as for the presence of *B. anthracis* spores, ricin, botulinum toxin and orthopox viruses. The Reader is a scanning fluorometer and data analysis system used for the measurement of fluorescence in RAMP immunoassay applications. The Reader can be operated on battery power or powered via an AC Adapter. The RAMP Test Cartridge is a single-use disposable, analyte specific cartridge that is used to detect the level of an analyte in an aqueous sample. The operator prepares the appropriate sample according to the Package Insert and then places an aliquot into the sample well of the Test Cartridge. The Test Cartridge is then inserted into the RAMP Reader, which analyzes the sample and provides a result.

Able to Detect the Following Organism/Toxins:
Bacillus anthracis (3)
Francisella tularensis (1)
Yersinia pestis (1)
Smallpox virus (3)
Orthopox virus (3)
Botulinum toxin A,B,E (3)
Ricin (3)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: RAMP assays are processed in disposable, single-use Test Cartridges. Each Cartridge houses an analyte-specific, mylar-backed nitrocellulose immunochromatographic strip on which the assay runs. The strip simultaneously runs a test reaction and an independent internal control reaction. The internal control has been incorporated into the RAMP System to provide reliable results by compensating for test-to-test variations. To perform an assay, the operator transfers a sample into the sample well of a Test Cartridge and inserts the Cartridge into the Reader. The sample is drawn by capillary action along the membrane. For example, in the Anthrax Test, BA spores present in the sample interact and bind with the mobile, fluorescently labeled anti-BA antibodies, forming an antibody-antigen complex. The complexes and labeled antibodies are subsequently captured at the detection and internal control zones. When the reaction in the Cartridge is complete, the Reader scans the test strip and detects fluorescence in the detection and the internal control zones and determines the concentration of BA spores. To accomplish this task, the Reader calculates the ratio between the concentrations of fluorescing particles in the detection and internal control zones. By calculating the final assay result as a ratio between the two measurements, the RAMP System automatically accounts for variations in sample and membrane properties. A "POSITIVE" or "NEGATIVE " test result is determined by the Reader. An assay result appears on the Reader's display within 15 minutes of inserting the Cartridge. The result can also be stored, printed, or uploaded to a laboratory, hospital or other information system.

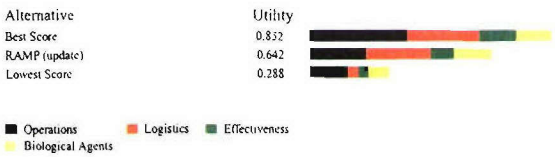
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

RAMP ranked in the middle third of all evaluated products for analytical laboratories and earned 61% of the utility points of the best score.

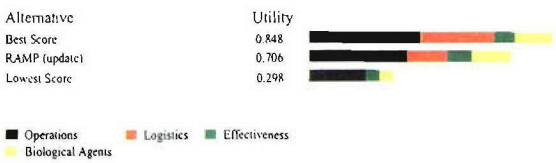
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

RAMP ranked in the middle third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

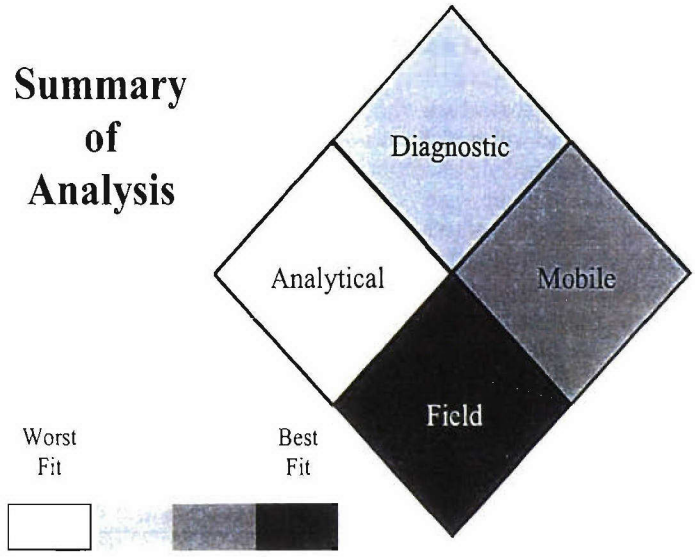
RAMP ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

RAMP ranked in the top third of all evaluated products for field use and earned 95% of the utility points of the best score.

Summary of Analysis



RAMP Evaluation Criteria Provided by Vendor

Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 sample/batch
- Less than 100 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- An afternoon of training
- No required set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- No service required
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1-3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- Sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $25.00/sample
$9,750.00/system or device

Response Biomedical Corp.
8081 Lougheed Highway
Burnaby, BC V5A 1W9 Canada
www.responsebio.com

Point of Contact: David Trotter
(604) 681-4101 ext. 210
Fax (604) 412-9830
dtrotter@responsebio.com

RAPID-Ruggedized Advanced Pathogen Identification Device

by Idaho Technology

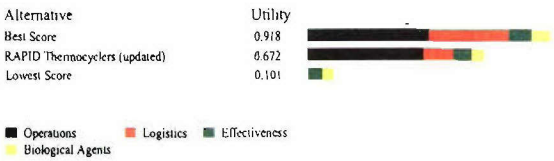
Description: RAPID is a fluorescent monitoring thermal cycler that is man-portable, impact resistant, and requires minimal training for operational use in military field hospital and other austere environments. The system can be made operational within 30 minutes of arrival on site (includes setup and warm-up time) and is designed to prevent operator exposure to the samples being processed while preserving sample integrity. The system has a feature for clinical identification of pathogenic agents. The identification feature applies specific identification technology to allow for pinpointing the presence of specific pathogens. The RAPID is used extensively by all branches of the US DoD for BW pathogen Identification and well as food borne illness identification. It is rugged and field portable with simple push button software for field use while maintaining an advanced user interface for Laboratory research applications.

Able to Detect the Following Organisms:
Bacillus anthracis (4)
E. coli 0157:H7 (4)
Francisella tularensis (4)
Yersinia pestis (4)
Brucella species (4)
Smallpox virus (2)
Orthopox virus (2)
VEE virus (2)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The RAPID is a high speed real-time air thermal-cycler that relies on specific DNA amplification for pathogen identification. We couple this with optimized freeze-dried reagents alleviating the need for any refrigeration or freezing of chemistry components for 6 months. We have validated freeze-dried assays for Anthrax, Brucella spp., Y. pestis, Tularemia, Salmonella, C.botulinum, Campylobacter, E.coli 0157, and L. monocytogenes.

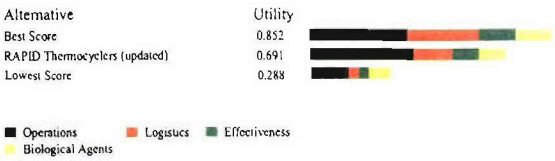
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

RAPID ranked in the top third of all evaluated products for analytical laboratories and earned 73% of the utility points of the best score.

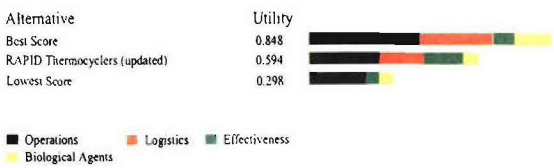
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

RAPID ranked in the top third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

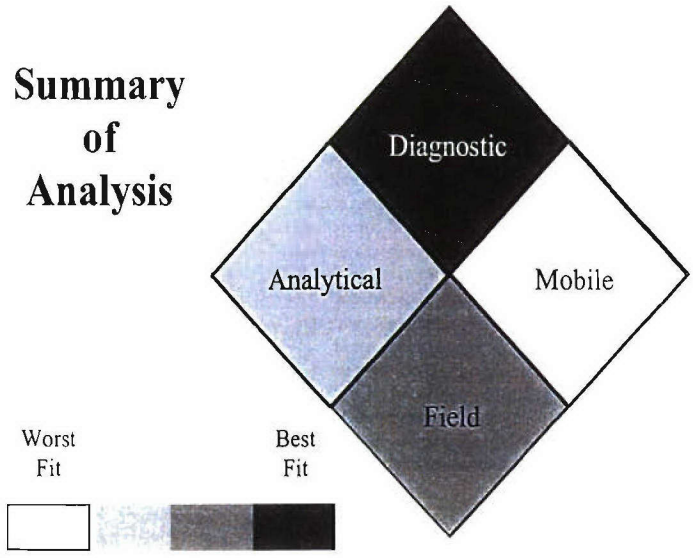
RAPID ranked in the middle third of all evaluated products for mobile laboratories and earned 70% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

RAPID ranked in the middle third of all evaluated products for field use and earned 79% of the utility points of the best score.

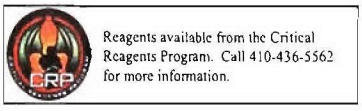
Summary of Analysis



RAPID Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications



System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 32 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- More than a day of training
- Less than 5 minutes required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Needs service every 6 months
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- Multiple centrifugation steps required
- Single shaking or vortexing step
- System able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

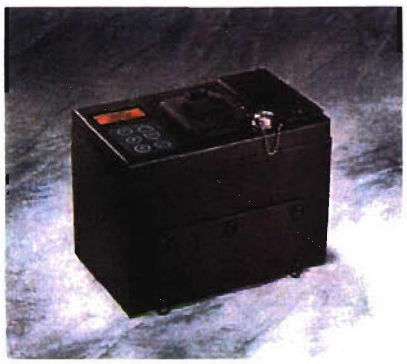
Cost: $16/sample (duplicate reactions)
$48,400 GSA/$ 60,000 non-GSA price/system or device

Idaho Technology
390 Wakara Way
Salt Lake City, UT 84108
www.idahotech.com

Point of Contact: Matt Scullion
(801) 736-6354 ext.327
fax. (801) 588-0507
matts@idahotech.com

RAPTOR

by Research International & BAE Systems



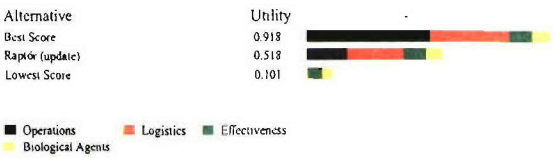
Description: The RAPTOR is a portable (14 lbs) MILSPEC-qualified bioassay system that was initially designed by Research International to U.S. Special Forces specifications and which is now being sold worldwide for evaluation as a biowarfare detection system. The battery-powered system can simultaneously detect the presence of up to four biological agents or toxins in a liquid sample at parts-per-billion concentration levels. It represents a novel integration of optics, fluidics, electronics, and software into one compact system that can automatically perform a user-defined, multistep, assay protocol using plastic optical waveguide biosensors mounted in a disposable assay coupon. The RAPTOR may be used in any context when an assay for a biological agent must be conducted in a short period of time with little or no sample preparation. The system is designed to be carried to a site and operated by non-technical personnel. Uses under active evaluation include both covert and overt operations by warfighters, homeland security applications such as first response, infrastructure protection and medical triage, and food and drinking water protection.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (4)
E. coli 0157:H7 (1)
Vibrio cholera (1)
Francisella tularensis (1)
Yersinia pestis (1)
Brucella species (2)
MS-2 bacteriophage (1)
Botulinum toxin A (1)
SEB (1)
Ricin (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The RAPTOR is a self-contained, 4-channel system for conducting these evanescent wave fluorimetric assays to monitor biological agents, toxins, explosives, and chemical contaminants. It can automatically perform a multi-step assay protocol based on the fluorescent detection of reactions occurring at the surface of four individual optical waveguide sensors mounted in a disposable coupon. The sensors function independently allowing four different assays to be performed on a single sample. The form factor of the waveguide sensor and the overall design of the RAPTOR make the system particularly well suited to performing fluoroimmunoassays conducted in the 'sandwich' format. Typically, a capture antibody is immobilized on the waveguide surface by physical adsorption. A sample is introduced and incubated for 1.5–7 minutes. The sample is then flushed and fluorophore-labeled secondary antibody is introduced to the waveguide. Following a second 1.5 minute incubation, the secondary antibody solution is recovered, the waveguide is rinsed, and the fluorescence signal is measured. This assay format makes it possible to detect a wide range of biomolecules, viruses, and bacteria with high specificity at 'ppb' concentrations. These miniature waveguide-based biosensors exhibit the sensitivity and specificity of an ELISA but tolerate very crude samples, exhibit extremely rapid assay times, consume minimal reagents, and are reusable. The sandwich assay format, as implemented with the RAPTOR, provides an assay protocol that is extremely resistant to sample contamination. First, essentially only fluorophore bound to the waveguide through a specific antibody-antigen-antibody reaction can be seen due to the evanescent wave excitation approach. Second, neither particulates nor soluble, fluorescent impurities will effect assay results since the fluorescent signal is detected after the waveguide has been rinsed.

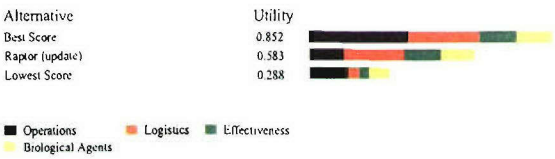
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

RAPTOR ranked in the bottom third of all evaluated products for analytical laboratories and earned 56% of the utility points of the best score.

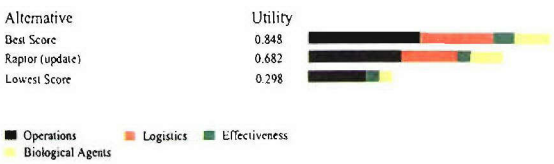
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

RAPTOR ranked in the middle third of all evaluated products for diagnostic laboratories and earned 68% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

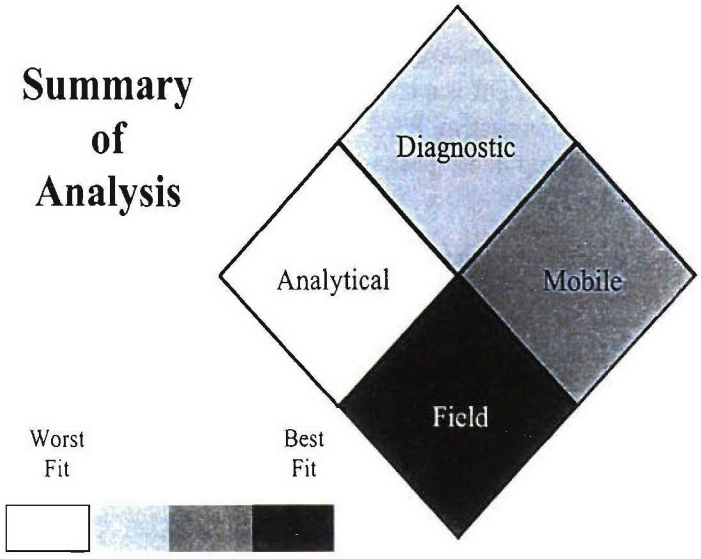
RAPTOR ranked in the top third of all evaluated products for mobile laboratories and earned 80% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

RAPTOR ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

Summary of Analysis



RAPTOR Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000-100,000 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- System or device uses batteries
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- A day of training
- 10-20 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- Water and/or bleach cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Once a year service required
- Expected life is 3-5 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a toaster
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components can be stored at 25°C to 45°C
- Performance of the device or system is not influenced by relative humidity

Cost: $1.00/sample
$49,000.00/system or device

Research International, Inc.
In partnership with BAE Systems, Inc
17161 Beaton Road SE
Monroe, WA 98272
www.resrchintl.com

Point of Contact: David McCrae
(360) 805-4930
fax. (360) 863-0439
davidmccrae@resrchintl.com

RAZOR

by Idaho Technology

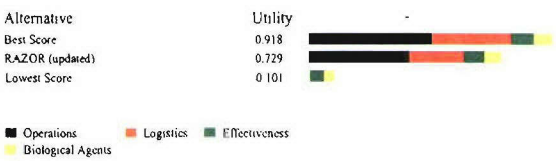
Description: Idaho Technology continues to set the standard in pathogen detection. RAZOR is a handheld, battery powered biological identification system. RAZOR uses IT's proven freeze dried reagents contained in pre-packaged pouches. RAZOR's dimensions are 4 x 8 x 12" (10 x 20 x 30 cm) and it weighs 10 lbs (4.5 kg).

Able to Detect the Following Organisms/Toxin:
Bacillus anthracis (4)
E. coli 0157:H7 (4)
Francisella tularensis (4)
Yersinia pestis (4)
Brucella species (4)
Smallpox virus (2)
Orthopox virus (2)
VEE virus (2)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The basis of RAZOR's technology is polymerase chain reaction (PCR), a method of DNA amplification. RAZOR's accuracy, portability and ease of use make it the ideal device for field and onsite detection. RAZOR also has a fluorimeter to measure DNA product and provide real-time detection. In a single RAZOR run, up to 12 samples can be analyzed (under 30 minutes) including positive controls, negative controls, and unknown samples.

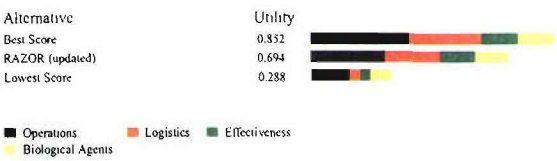
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

RAZOR ranked in the top third of all evaluated products for analytical laboratories and earned 79% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

RAZOR ranked in the top third of all evaluated products for diagnostic laboratories and earned 81% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

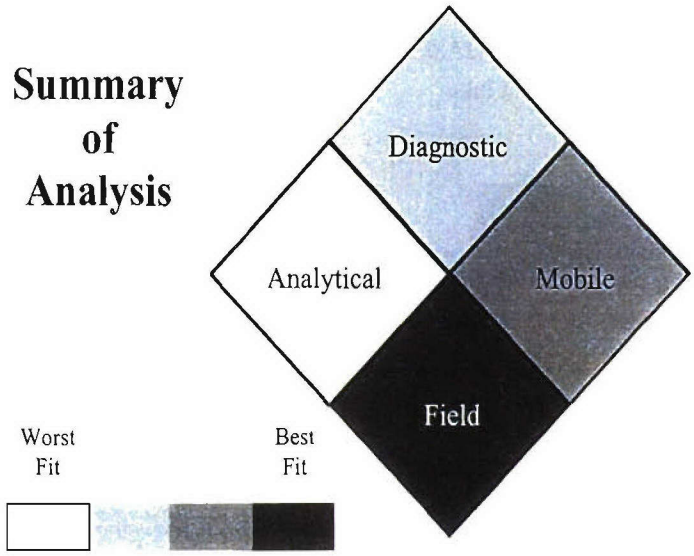
RAZOR ranked in the top third of all evaluated products for mobile laboratories and earned 83% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

RAZOR ranked in the top third of all evaluated products for field use and earned 93% of the utility points of the best score.

Summary of Analysis



RAZOR Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 30 and 40 minutes
- 2 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a semi automated system with some effort

Training/Speed/Manpower:
- A day of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Less than once a year service required
- Expected life is 3-5 years
- No daily assurance procedures required

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at room temperature
- Performance not influenced by relative humidity

Cost: $30.00/sample
Approx. $37,000/system or device

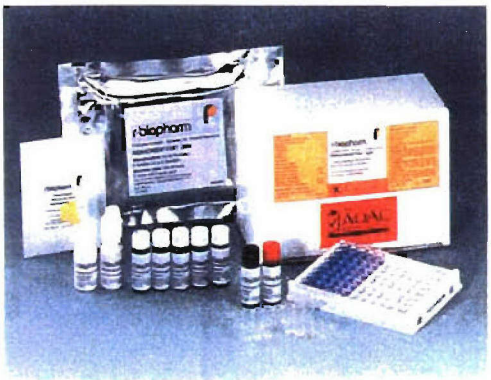
Idaho Technology
390 Wakara Way
Salt Lake City, UT 84108
www.idahotech.com

Point of Contact: Matt Scullion
(801) 736-6354 ext 327
fax. (801) 588-0507
matts@idahotech.com

RIDASCREEN ELISA Test Kit

by R-Biopharm, Inc.

Description: RIDASCREEN test kits are all microwell ELISA based test kits.



Able to Detect the Following Toxins:
SEB (1)
T-2 toxin (1)
Saxitoxin (1)
Shigatoxin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The basis of the test is an antigen-antibody reaction. The wells in the microtiter strips are coated with specific antibodies to mouse antibodies. By adding standards or the sample solutions, enzyme labeled toxin (enzyme conjugate), and anti-toxin antibodies, free and enzyme labeled toxin compete for the antibody binding sites of the anti-toxin antibodies, which themselves are bound simultaneously by the capture antibodies on the microtiter plate. Any unbound enzyme conjugate is then removed in a washing step. Enzyme substrate (urea peroxide) and chromogen (tetramethylbenzidine) are added to the wells and incubated. Bound enzyme conjugate converts the colorless chromogen into a blue product. The addition of the stop reagent leads to a color change from blue to yellow. The measurement is made photometrically at 450 nm (optional reference wavelength ³ 600 nm). The absorption is inversely proportional to the toxin concentration in the sample.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
RIDASCREEN ELISA (unchanged)	0.299
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

RIDASCREEN ELISA Test Kit ranked in the bottom third of all evaluated products for analytical laboratories and earned 33% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
RIDASCREEN ELISA (unchanged)	0.381
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

RIDASCREEN ELISA Test Kit ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 45% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
RIDASCREEN ELISA (unchanged)	0.519
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

RIDASCREEN ELISA Test Kit ranked in the middle third of all evaluated products for mobile laboratories and earned 61% of the utility points of the best score.

Field Use Ranking

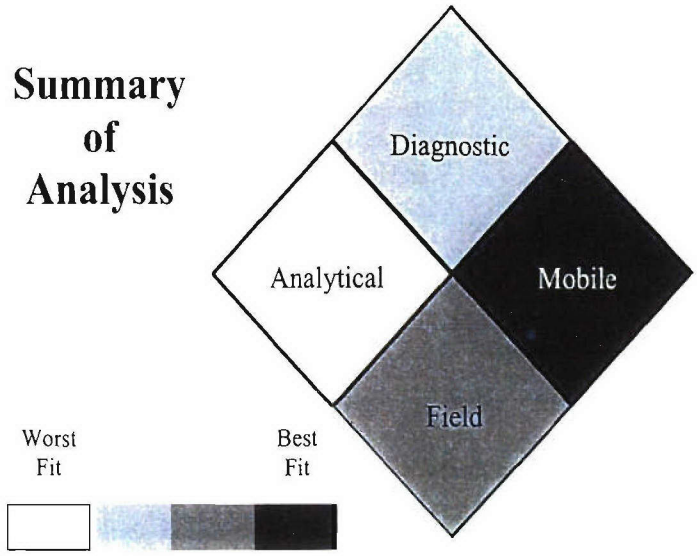
Alternative	Utility
Best Score	0.864
RIDASCREEN ELISA (unchanged)	0.524
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

RIDASCREEN ELISA Test Kit ranked in the bottom third of all evaluated products for field use and earned 61% of the utility points of the best score.

Summary of Analysis



RIDASCREEN ELISA Test Kit Evaluation Criteria Provided by Vendor

Sensitivity:
- NA CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- Single shaking or vortexing step
- System always able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device does require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 32 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- 5-10 minutes required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Once a year service required
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 25°C to 37°C
- Components must be stored at 4°C
- Peak performance of the device or system is at normal relative humidity only

Cost: $10.00/sample
$450.00/system or device

R-Biopharm, Inc.
7950 Old US 27 South
Marshall, MI 49068
www.r-biopharm.com

Point of Contact: Sean Tinkey
(269) 789-3033
fax. (269) 789-3070
s.tinkey@r-biopharm.com

Rotor-Gene 3000 Real Time DNA Amplification System

by Corbett Research

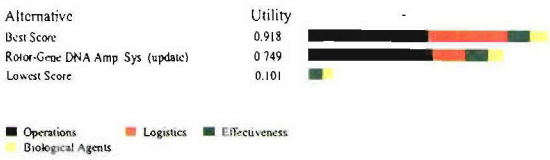
Description: The Rotor-Gene is designed to measure an increase of amplified DNA fragments for quantitative and qualitative analysis. It uses chemistry platforms to detect any nucleic acid sequence from multiple sources (i.e. bacteria, viruses and spores from blood, tissue, soil and environmental samples.)

Technology: Real-time detection system using various DNA amplification methods comprised of a thermal cycler to control the temperature of samples/reagents and a fluorometer to take fluorescent measurements at any time point. The machine measures DNA amplification via fluorescence to determine quantities of starting templates of genetic markers. The Rotor-Gene is an open chemistry platform capable of running isothermal assays (Invader, Roling Circle, NASBA, TMA) and temperature cycling assays such as PCR with all the current chemistry platforms (sybr, dual-labeled probes, molecular beacons, scorpions, hybridization probes). The flexible and user friendly software of the Rotor-Gene allows for data acquisition at any point in the cycling with multiple filter combinations. Using multiple LED's for excitation and a PMT for detection, the unit can multiplex up to 4 dyes in a single tube. The 6 emission filters on the standard system allow for a wide range of fluors to be detected (510, 555, 610, 585hp, 610hp 660hp).

Able to Detect the Following Organisms:
Bacillus anthracis (1)
Francisella tularensis (1)
Yersinia pestis (1)
Brucella species (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

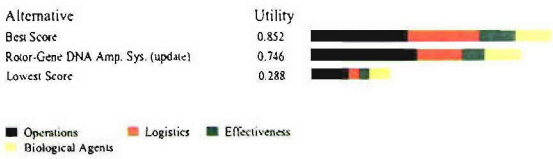
Analytical Laboratory Ranking



Preference Set – Analytical Laboratory

Rotor-Gene Real Time DNA Amplification System ranked in the top third of all evaluated products for analytical laboratories and earned 82% of the utility points of the best score.

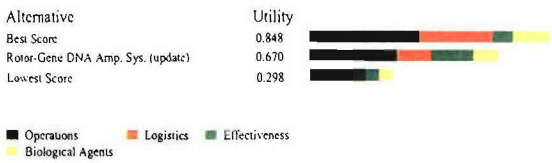
Diagnostic Laboratory Ranking



Preference Set – Diagnostic Laboratory

Rotor-Gene Real Time DNA Amplification System ranked in the top third of all evaluated products for diagnostic laboratories and earned 88% of the utility points of the best score.

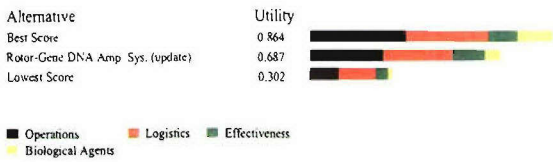
Mobile Laboratory Ranking



Preference Set – Mobile Laboratory

Rotor-Gene Real Time DNA Amplification System ranked in the top third of all evaluated products for mobile laboratories and earned 79% of the utility points of the best score.

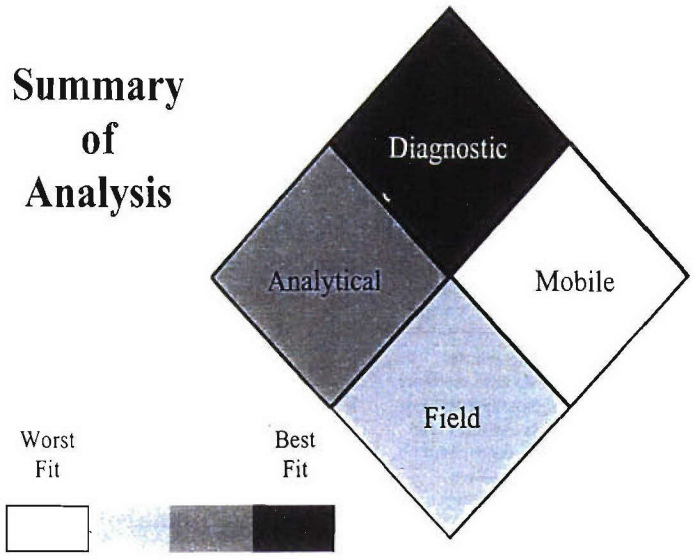
Field Use Ranking



Preference Set – Field Use

Rotor-Gene Real Time DNA Amplification System ranked in the middle third of all evaluated products for field use and earned 80% of the utility points of the best score.

Summary of Analysis



Rotor-Gene 3000 Real Time DNA Amplification System Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- One additional pieces of equipment needed

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device requires an external air source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection between 40 and 50 minutes
- 32 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system could be adapted into a semi-automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solutions or buffers used
- 2 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- Between 5 and 25 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

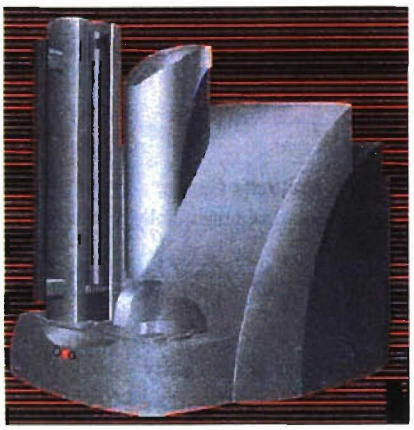
Cost: Approx. $1.00/sample
$34,990.00/system or device

Corbett Research
1/14 Hilly Street
Mortlake, NSW 2137 Australia
www.corbettresearch.com

Point of Contact: John Corbett
011-612-973-613-20
fax. 011-612-973-613-64
john@corbettresearch.com

Sector Imager 6000

by Meso-Scale Discoveries



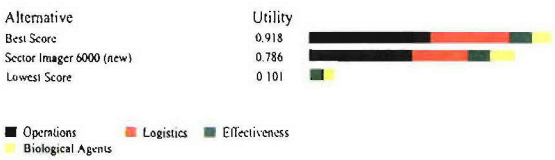
Description: The Sector Imager 6000 (SI6000) is an electrochemiluminesence (ECL) based system using assay reagents that are directly immobilized on the electrode used to induce ECL. The carbon-based electrodes are in the form of standard microtiter plates with 96, 384 and 1,536 wells per plate. The centerpiece of this system is the cooled-CCD camera and telecentric lens which enable rapid, highly sensitive measurements. In addition, the use of screen-printed electrodes has enabled MSD to produce a machine capable of detecting of multiple analytes in one well (multiplexing.) The system was originally designed for use by the pharmaceutical industry in support of their high throughput screening efforts. On top of superior detection capabilities across the spectrum of potential bioagents (viruses, bacteria and toxins,) the MSD instruments are easy to use and capable of providing results in 30 minutes for over one thousand tests. The SI 6000 is perfectly suited for the needs of central lab demanding highly sensitive measurements in a rapid pace for a large volume of samples.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (1)
E. coli O157:H7 (1)
Francisella tularensis (1)
Yersinia pestis (1)
VEE virus (1)
Botulinum toxin A (1)
SEB (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Electrochemiluminescence (ECL) is a well-developed, commercial technology for the detection and study of biomolecular interactions and function. ECL-based assays employ labels that emit light when electrochemically oxidized or reduced under appropriate chemical conditions. The existence of small, stable and highly efficient ECL labels makes the technique robust, sensitive and easy to implement. ECL detection is already widely used in the military for detection of biological agents. We have adapted the technology to allow ECL assays to be carried out on inexpensive disposable electrodes in a format that is compatible with multiplexed array-based measurements. Our systems are currently being evaluated at the Edgewood Chemical and Biological Center and USAMRIID. Assays are carried out on proprietary Multi-Array plates having integrated electrodes that act as both a capture surface and an energy source for electrochemiluminescence excitation. The spatial control inherent in ECL induction and imaging detection allows for multiplexed array based measurement employing patterned arrays of binding reagents on an electrode surface. A variety of plate formats have been designed to suit the broad range of needs of drug discovery and biological research – from the standard 96, 384 and 1536-well formats to custom Multi-Spot plates for performing multiple measurements in each well of specially designed 96 and 24-well plates. The 96-well plates are capable of detecting 4, 7 or 10 analytes per well. The 24-well plates are capable of detecting 25, 64 or 100 analytes per well. The plates are manufactured using well-established scalable techniques such as screen-printing that allow for high volume manufacturing at low cost. These assays are capable of highly sensitive detection with broad dynamic ranges. The SI600 is can perform over 1,000 determinations per minute.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Sector Imager 6000 ranked in the top third of all evaluated products for analytical laboratories and earned 86% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

Sector Imager 6000 ranked in the top third of all evaluated products for diagnostic laboratories and earned 100% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

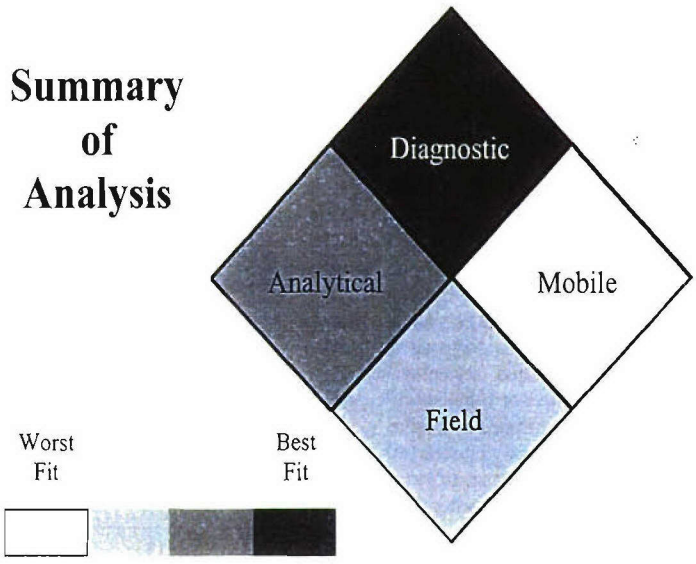
Sector Imager 6000 ranked in the middle third of all evaluated products for mobile laboratories and earned 74% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

Sector Imager 6000 ranked in the top third of all evaluated products for field use and earned 85% of the utility points of the best score.

Summary of Analysis



Sector Imager 6000

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirements
- The system or device does not require water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in less than 20 min
- 384 samples/batch or higher
- Less than 100 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 0-1 solution or buffer used
- 1 components
- No cleaning required

Maintenance:
- 2 consumable or expendable needed
- Needs service less than once a year
- Expected life measure of 5-10 years
- No daily quality assurance procedures necessary

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- A single shaking or vortexing step
- System can interpret raw data or call a positive through internal software
- Assays available, and capable of detecting four or more agents or toxins within the same well
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Between 200-500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- The influence of relative humidity on the performance of the device or system is unknown

Cost: <$4.00/assay
$250,000/device or system

Meso-Scale Discoveries
9238 Gaither
Gaithersburg, MD 20878
www.meso-scale.com

Point of Contact: Vit Vasista
(240) 631-2522 x4622
(240) 632-2219 fax
vvasista@meso-scale.com

SMART (flowthrough)

by New Horizons Diagnostics Corp.

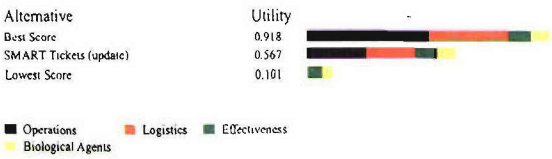
Description: New Horizons Diagnostics (NHD) Corporation's SMART-II (lateral flow) screening assay includes a plastic cassette, which contains all the active ingredients, a bottle of Chase Buffer, and a plastic dropper. The assay is designed to act as a screen for the presence of a target organism. It is designed for environmental samples, not for human samples or for the diagnosis of disease. No known rapid screening assay is 100% sensitive or 100% specific; results should be confirmed by another method. The SMART assay must be utilized with the SWIPE collection system or similar validated collection system.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (2)
E.coli 0157:H7 (2)
Francisella tularensis (2)
Vibrio cholera (2)
Burkholderia mallei (1)
Burkholderia pseudomallei (1)
Yersinia pestis (2)
Coxiella burnetti (1)
Brucella species (2)
Rift Valley fever virus (1)
Smallpox virus (1)
VEE virus (1)
Botulinum toxins A,B (2)
Botulinum toxin E (1)
SEB (2)
Ricin (2)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: In the Lateral Flow format, which is similar to an OTC pregnancy test, antibody coated colloidal gold particles are applied to a membrane surface and dried. When a test sample is applied, the gold conjugate reacts with the antigen that is present as it migrates across the length of the membrane to where it encounters a zone of capture antibody. Those antibody-gold conjugates, which have bound to antigen in the test sample, are then bound in the capture antibody zone, presenting a visually detectable line of color and indicating a positive test result. Sufficient antibody will be available to permit passage through the capture zone. These particles will then contact an area coated with an appropriate IgG fraction, where they will bind, producing a visible line of color. This line is the Control or Positive Reading Guide Line. The intent is to indicate that the reagents and test sample have successfully migrated the length of the membrane. Additionally, the "C" (Control) line provides the user/operator an example of what a positive should look like.

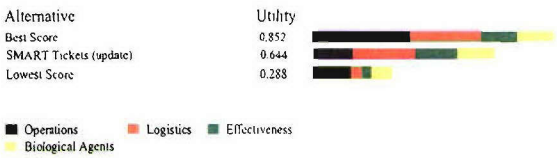
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

SMART ranked in the middle third of all evaluated products for analytical laboratories and earned 62% of the utility points of the best score.

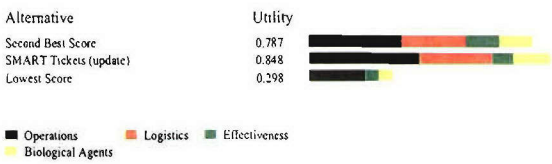
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

SMART ranked in the middle third of all evaluated products for diagnostic laboratories and earned 76% of the utility points of the best score.

Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

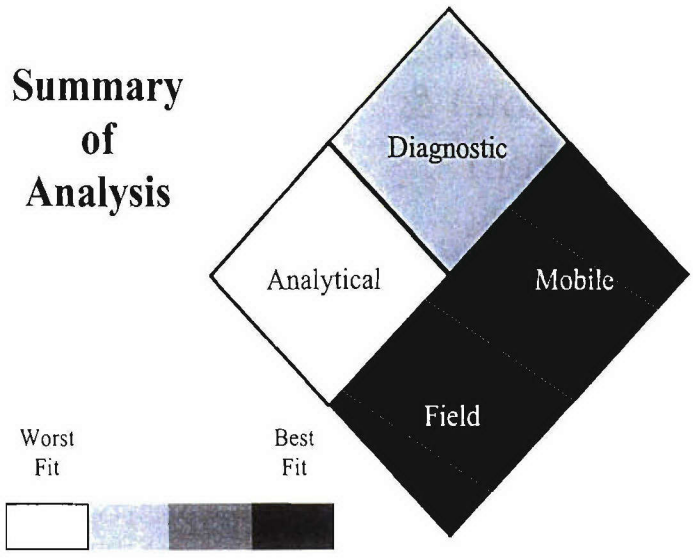
SMART ranked in the top third of all evaluated products for mobile laboratories and earned 100% of the utility points of the best score.

Field Use Ranking

Preference Set = Field Use

SMART ranked in the top third of all evaluated products for field use and earned 100% of the utility points of the best score.

Summary of Analysis



SMART (flowthrough) Evaluation Criteria Provided by Vendor

Sensitivity:
- 10,000 - 100,000 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- No electrical requirements
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 samples/batch
- Less than 100 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 0-1 solution or buffer used
- 2 components
- NA cleaning required

Maintenance:
- 2 consumables or expendables needed
- No service required
- NA expected life
- No daily quality assurance procedures

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System never able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

Cost: $15.00-32.00/sample
$15.00-32.00/system or device

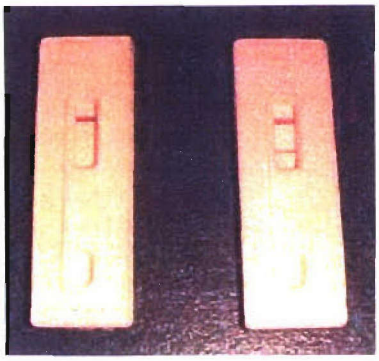
New Horizons Diagnostic Corp.
9110 Red Branch Rd.
Columbia, MD 21045
www.NHDiag.com

Point of Contact: David Trudil
(410) 992-9357 ext. 222
fax. (410) 992-0328
NHDiag@aol.com

Additional Information: SMART II (lateral flow) & SWIPE (collection)

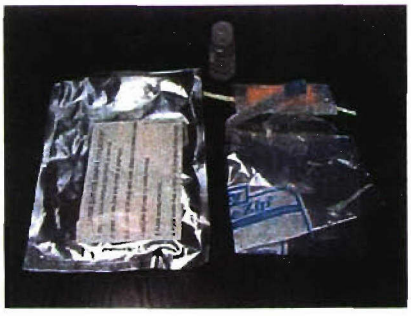
SMART II (lateral flow)

by New Horizons Diagnostics Corp.



Description: New Horizons Diagnostics (NHD) Corporation's SMART-II ™ (lateral flow) screening assay includes a plastic cassette, which contains all the active ingredients, a bottle of Chase Buffer, and a plastic dropper. The assay is designed to act as a screen for the presence of a target organism. It is designed for environmental samples, not for human samples or for the diagnosis of disease. No known rapid screening assay is 100% sensitive or 100% specific; results should be confirmed by another method. The SMART assay must be utilized with the SWIPE collection system or similar validated collection system, such as the BiSKit Sampling Kit available from Quicksilver Analytics.

Technology: In the Lateral Flow format, which is similar to an OTC pregnancy test, antibody coated colloidal gold particles are applied to a membrane surface and dried. When a test sample is applied, the gold conjugate reacts with the antigen that is present as it migrates across the length of the membrane to where it encounters a zone of capture antibody. Those antibody-gold conjugates, which have bound to antigen in the test sample, are then bound in the capture antibody zone, presenting a visually detectable line of color and indicating a positive test result. Sufficient antibody will be available to permit passage through the capture zone. These particles will then contact an area coated with an appropriate IgG fraction, where they will bind, producing a visible line of color. This line is the Control or Positive Reading Guide Line. The intent is to indicate that the reagents and test sample have successfully migrated the length of the membrane. Additionally, the "C" (Control) line provides the user/operator an example of what a positive should look like.



SWIPE (collection)

by New Horizons Diagnostics Corp.

Description: In conjunction with the needs of the US Army and First Responders, NHD developed a patented a line of collection kits that have been validated for utilization with the SMART II and PROFILE detection assays. In addition to being tamper evident, the kits contain a set of instructions and the plastics and buffers needed for collecting and archiving the sample. The collection kits contain laSWIPE-1 (Large Surface), SWIPE –2 (Small Surface/Powders), SWIPE-3 (liquid), SWIPE-4 (Air), and SPK (Sample Processing Kit -for extra dirty samples).

Smart Cycler

by Cepheid

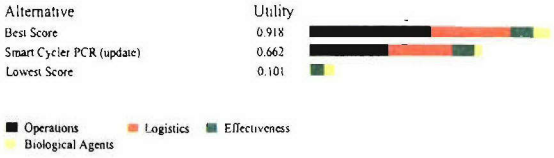
Description: The Smart Cycler is a real-time, integrated DNA/RNA amplification, detection, and analysis system. Quantitation of the amplified product is achieved by measuring the increase in fluorescence during the PCR reaction. This is accomplished by incorporating an intercalating dye, such as SYBR Green, a fluorogenic probe such as a TaqMan hybridization probe or a molecular beacon, or fluorogenic primers such as Amplifluor or Scorpion primers. Features of the instrument include: **Random Access**: Up to sixteen different cycling protocols can be performed simultaneously in one processing block. Multiple experimental runs can be started at different times, allowing several operators to use the instrument concurrently. **Fast turnaround time:** Rapid thermal cycling is possible due to efficient heating and cooling of the sample using the specially designed tubes to achieve a high surface-to-volume ratio. **Accuracy:** Reduce the number of replicates with reliable quantification of target DNA by identifying the earliest PCR cycle in which the fluorescence signal is above background. Irreproducible results from endpoint analysis are eliminated.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (3)
E. coli 0157:H7 (1)
Vibrio cholera (1)
Francisella tularensis (1)
Burkholderia mallei (1)
Yersinia pestis (1)
Coxiella burnetti (1)
Rickettsia prowazekii (1)
Brucella species (1)
Smallpox virus (1)
VEE virus (1)
Hanta virus (1)
Dengue fever virus (1)
Orthopox virus (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The Smart Cycler is a real-time, integrated DNA/RNA amplification, detection, and analysis system. Quantitation of the amplified product is achieved by measuring the increase in fluorescence during the PCR reaction. This is accomplished by incorporating an intercalating dye, such as SYBR Green, a fluorogenic probe such as a TaqMan hybridization probe or a molecular beacon, or fluorogenic primers such as Amplifluor or Scorpion primers. Features of the instrument include: **Random Access**: Up to sixteen different cycling protocols can be performed simultaneously in one processing block. Multiple experimental runs can be started at different times, allowing several operators to use the instrument concurrently. **Fast turnaround time:** Rapid thermal cycling is possible due to efficient heating and cooling of the sample using the specially designed tubes to achieve a high surface-to-volume ratio. **Accuracy:** Reduce the number of replicates with reliable quantification of target DNA by identifying the earliest PCR cycle in which the fluorescence signal is above background. Irreproducible results from endpoint analysis are eliminated.

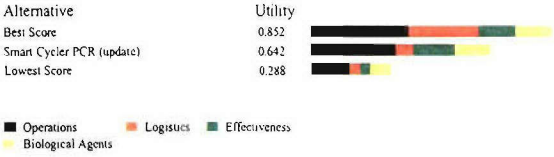
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Smart Cycler ranked in the middle third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.

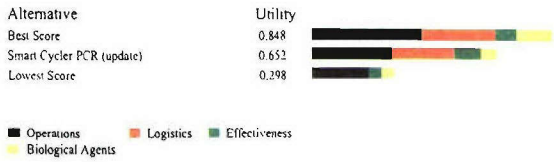
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Smart Cycler ranked in the middle third of all evaluated products for diagnostic laboratories and earned 75% of the utility points of the best score.

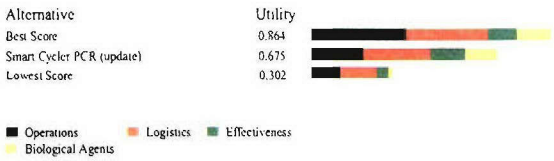
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Smart Cycler ranked in the top third of all evaluated products for mobile laboratories and earned 77% of the utility points of the best score.

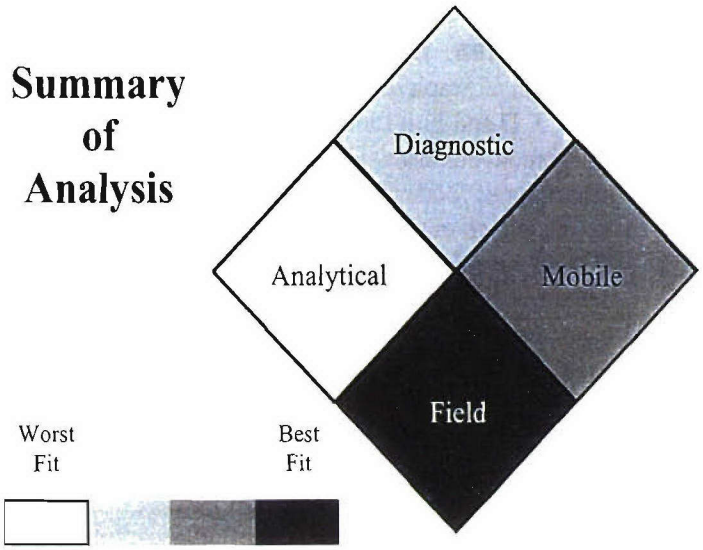
Field Use Ranking



Preference Set = Field Use

Smart Cycler ranked in the middle third of all evaluated products for field use and earned 78% of the utility points of the best score.

Summary of Analysis



Smart Cycler Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- System or device has 110V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 minutes
- 32 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could be adapted to a fully automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- 5-10 minutes required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 2 solution or buffer used
- 3 components
- No cleaning required

Maintenance:
- 4 consumables or expendables needed
- Once a year service required
- Expected life is greater than 10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a carry-on luggage
- Between 5 and 25 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- A single centrifugation step
- No shaking or vortexing steps
- System is able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Peak performance of the device or system is at normal humidity conditions only

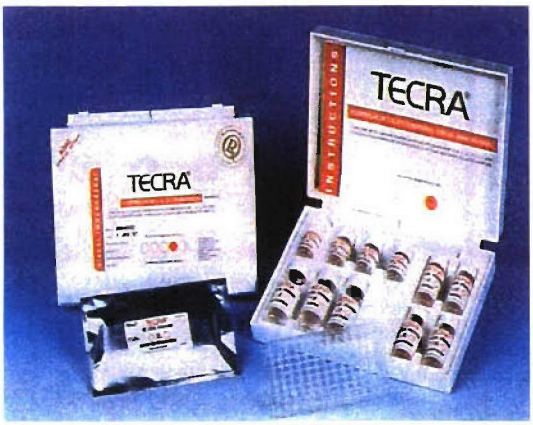
Cost: $2.50/sample
$31,000.00-34,000.00/system or device

Cepheid
904 Carribean Drive
Sunnyvale, CA 94089
www.smartcycler.com

Point of Contact: Jeffrey Ryan
(888) 838-3222
Fax: (408) 734-1260
ryan@cepheid.com

Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA)

by TECRA International Pty Ltd



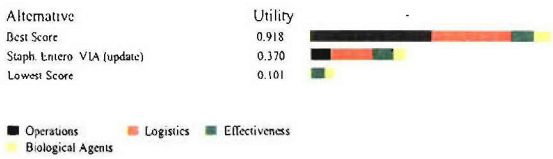
Description: A rapid and simple screening test for detection of Staphylococcal Enterotoxins A, B, C1, C2, C3, D and E in food, food related samples and enrichment cultures. The kit is designed for the direct screening of foods for the presence of any of the seven toxins, which may be detected at concentrations as low as 1 ng per mL within 4 hours. However, the kit cannot be used for the identification of a specific toxin type. For this purpose, the TECRA SET ID kit may be used. The ELISA can be used manually and the results read by eye. However, it can also be semi-automated with the use of microtitre plate readers and washers or fully automated for large scale testing. The kit is available in a 48 and 96 well formats.

Able to Detect the Following Toxins:
Staphylococcal EntertoxinsA, B, C1, C2, C3, D and E (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The TECRA SET VIA is an Enzyme-linked Immunoassay (ELISA) performed in a sandwich configuration.

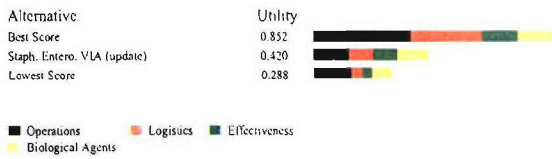
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Staphylococcal Enterotoxin Visual Immunoassay ranked in the bottom third of all evaluated products for analytical laboratories and earned 40% of the utility points of the best score.

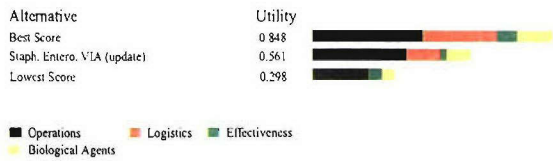
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Staphylococcal Enterotoxin Visual Immunoassay ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 49% of the utility points of the best score

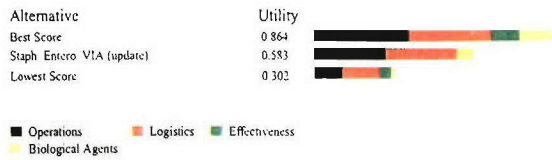
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Staphylococcal Enterotoxin Visual ranked in the middle third of all evaluated products for mobile laboratories and earned 66% of the utility points of the best score.

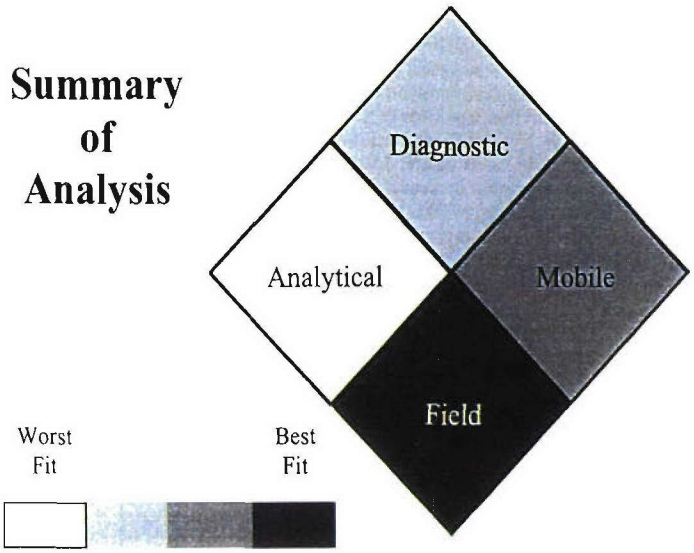
Field Use Ranking



Preference Set = Field Use

Staphylococcal Enterotoxin Visual Immunoassay ranked in the middle third of all evaluated products for field use and earned 67% of the utility points of the best score.

Summary of Analysis



Staphylococcal Enterotoxin (SET) Visual Immunoassay (VIA) Evaluation Criteria Provided by Vendor

Sensitivity:
- NA CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- No electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection greater than 60 minutes
- 384 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is designed for single use
- More than 4 solutions or buffers used
- 5 or more components
- NA cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- No service required
- Expected life NA
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Less than 1 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation step
- No shaking or vortexing steps
- System not able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting multiple biological agents or toxins within the same test
- Two additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 4°C to 45°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $7.00/sample
$306.00 for 48 wells, $556.00 for 96 wells/system or device

TECRA International Pty Ltd
13 Rodborough Rd.
Frenchs Forest, NSW 2086 Australia
www.tecra.net

Point of Contact: Nick Vale
+61 2 8977011
fax. +61 2 9453 3422
nick.vale@tecra.net

Stations of Robotic Monitoring (STORM)

by Edgewood Chemical Biological Center

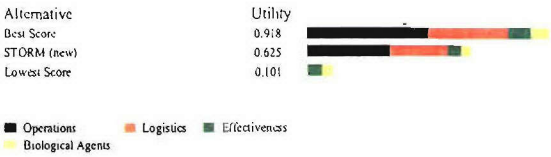
Description: The STORM (STations Of Robotic Monitoring) was designed at ECBC to provide a reliable, high-throughput means of sample screening for biological warfare agents. Both the mobile and stationary analytical labs employ the STORM concept. STORM utilizes the "lessons learned" from a previous DOD effort, the Automated Biological Agent Testing System (ABATS). STORM utilizes the DNA extraction method from ABATS, but eliminates the full-system integration feature. This modification allows greater flexibility when dealing with an inconsistent number of samples. The STORM mobile laboratory, designed in conjunction with and manufactured by ENG Mobile Systems Inc. (Concord, CA), is a 24- foot, 5th -wheel trailer with custom modifications for the accommodation of the Biomek FX automated liquid handling system (Beckman Coulter, Inc.), M1R analyzer (BioVeris Corporation), and ABI 7900 (Applied Biosystems, Inc.). It is equipped with a 6-foot Class II/B2 biological safety cabinet and a Class III glove box with outside access port to a pass-through chamber. The Biomek is contained within a HEPA-filtered chamber in order to protect the environment and operators from aerosols generated by the Biomek during the liquid handling process.

Able to Detect the Following Organisms/Toxins:
Bacillus anthracis (4)
Francisella tularensis (4)
Yersinia pestis (4)
Brucella species (4)
Orthopox virus (4)
Smallpox virus (4)
VEE virus (4)
Botulinum toxin A (4)
SEB (4)
Ricin (4)

Technology: Samples are analyzed by complimentary testing using both real time polymerase chain reaction (PCR) and electrochemiluminescent (ECL) technologies concurrently. The majority of the PCR assays were developed at ECBC and part of the JPEO-CBD Critical Reagent Repository (CRP). ECL assays are manufactured by BioVeris Corporation using CRP antibodies. Targets analyzed are determined by customer requirements, and targets can be changed or increased. Sample processing of 1-64 samples for all seven targets is completed within an 8 hour work day.

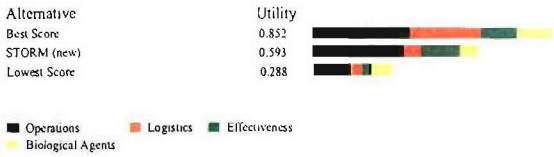
(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Analytical Laboratory Ranking



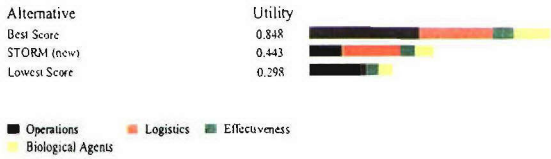
STORM ranked in the middle third of all evaluated products for analytical laboratories and earned 68% of the utility points of the best score.

Diagnostic Laboratory Ranking



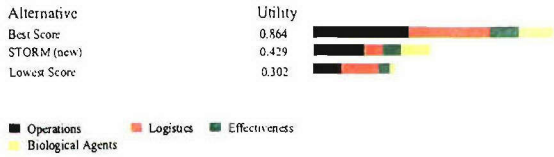
STORM ranked in the middle third of all evaluated products for diagnostic laboratories and earned 70% of the utility points of the best score.

Mobile Laboratory Ranking



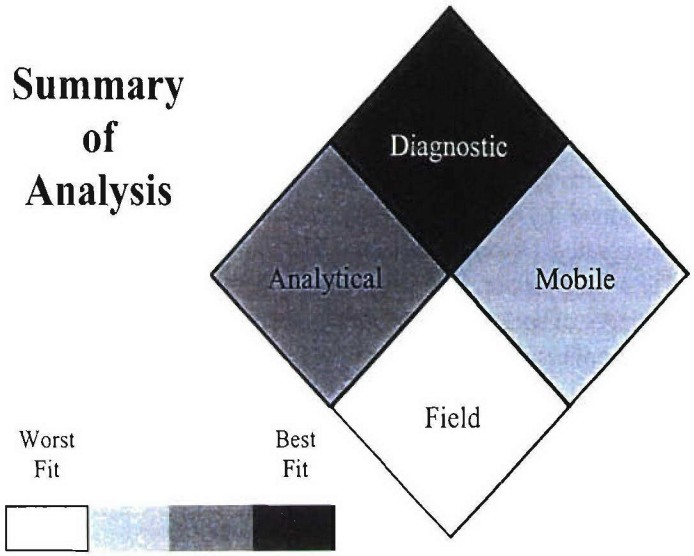
STORM ranked in the bottom third of all evaluated products for mobile laboratories and earned 52% of the utility points of the best score.

Field Use Ranking



STORM ranked in the bottom third of all evaluated products for field use and earned 50% of the utility points of the best score.

Summary of Analysis

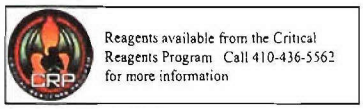


Stations of Robotic Monitoring (STORM)

Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Expected to be ready for commercialization within three or more calendar years
- A few systems or devices exist (brass board)



Ease of use/Utility
- Cannot view results "in real time"
- There are multiple centrifugation steps
- There are multiple shaking or vortexing steps .
- System can interpret raw data or call a positive through internal software
- Assay available, and capable of detecting four or more biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

System requirements:
- System or device has 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in greater than 60 min
- 96 samples/batch or higher
- Greater than 250 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- More than a day of training
- 10-20 min required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- More than 4 solution or buffer used
- 5 or more components
- General decontamination with bleach is the only cleaning requirement

Maintenance:
- 5 or more consumable or expendable needed
- Needs service once a year
- Expected life measure of greater than 10 years
- 10-20 minutes required for daily quality assurance procedures

Transportation:
- Larger than a home dishwasher
- More than 50 kg
- Shelf life between 6 months and 1 year

Cost: $300/sample
Approximately $900,000/device or system

Edgewood Chemical Biological Center
AMSRD-ECB-CB, Building E3330
Aberdeen Proving Ground, MD 21010
www.ecbc.army.mil

Point of Contact: Ray Mastnjak
(410) 436-4735
raymond.mastnjak@us.army.mil

Threshold System

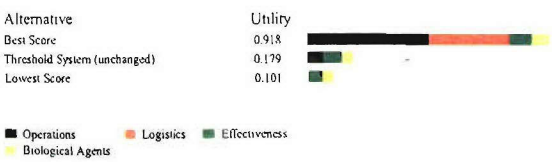
by Molecular Devices

Description: The Threshold system is used to detect and quantitate contaminants in biopharmaceuticals and sequence-specific DNA. Contaminants commonly analyzed with the Threshold system include total DNA, host cell proteins, bovine contaminants (BSA, IgG, insulin, transferrin), Proteins A and G, Bio-warfare agents, and any unique protein that can be bound by antibodies. The military uses Threshold for its Biological Integrated Detection System (BIDS). The technology is also used in ETG's BioDetector. The Threshold system's contaminant assays' proven advantages of speed, reproducibility, and reliability are incorporated into these new applications.

No Formal Detection Assay Available

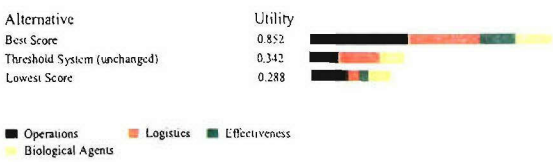
Technology: The sample containing the analyte of interest is incubated with the appropriate binding proteins or oligonucleotide probes. The analyte will be bound by the binding proteins or hybridized to the probes to form a complex. The sample mixture is then filtered through a membrane where the analyte complex is captured and separated from the sample. The captured analyte complex will contain enzyme proportional to the amount of complexed analyte. The membrane is inserted into the Threshold reader which contains the silicon sensor. A kinetic measurement of the enzyme activity is completed in 90 seconds. This data is then processed by the Threshold software and quantitation is provided.

Analytical Laboratory Ranking



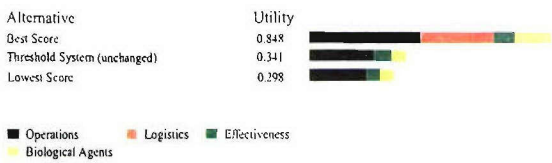
Threshold System ranked in the bottom third of all evaluated products for analytical laboratories and earned 19% of the utility points of the best score.

Diagnostic Laboratory Ranking



Threshold System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 40% of the utility points of the best score.

Mobile Laboratory Ranking

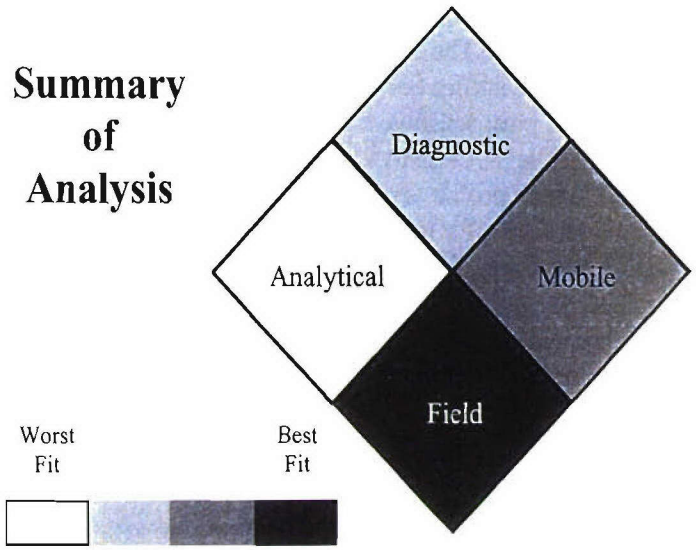


Threshold System ranked in the bottom third of all evaluated products for mobile laboratories and earned 40% of the utility points of the best score.

Field Use Ranking

Threshold System ranked in the bottom third of all evaluated products for field use and earned 58% of the utility points of the best score.

Summary of Analysis



Threshold System Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Is commercially available and meets military specifications

System requirements:
- System or device has 110V and 220V electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or approach is not amendable to automation

Training/Speed/Manpower:
- More than a day of training
- Less than 5 minutes required for set-up
- Greater than 12 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- More than 4 solutions or buffers used
- 5 or more components
- No cleaning required

Maintenance:
- 5 or more consumables or expendables needed
- Once a year service required
- Expected life is greater than 10 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a carry-on luggage suitcase
- More than 50 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Can view results "in real time"
- Single centrifugation steps may be required
- Multiple shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- Four or more additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Unknown BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C and frozen
- Performance of the device or system is not influenced by relative humidity

Cost: $3.25/sample
$50,000.00/system or device

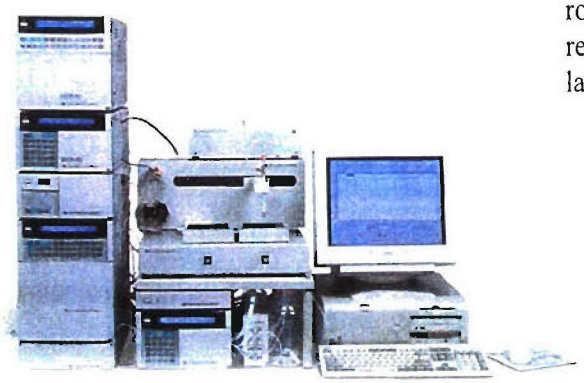
Molecular Devices
1311 Orleans Dr.
Sunnyvale, CA 95128
www.moleculardevices.com

Point of Contact: Emil Beitsayad
(408) 548-6326
fax. (408) 747-3601
Beitsayad@moldev.com

Transgenomic WAVE System

by Transgenomic

Description: The WAVE System is a mutation discovery system. It identifies SNP, insertions and deletions and is one of the most sensitive mutation discovery methods known. The WAVEMAKER software provides a melting curve, a melt profile and the prediction of the temperature to begin screening for mutation detection, by entering the DNA sequence. WAVE Systems are fully automated, robust, versatile and cost effective, meeting the critical requirements of leading academic and biopharmaceutical laboratories worldwide.

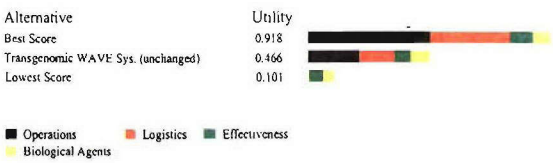


Able to Detect the Following Organisms/Toxin:
Bacillus anthracis (1)
Yersinia pestis (1)
Shigatoxin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The Transgenomic WAVE System is a DHPLC (Denaturing-High Performance Liquid Chromatography) system. The system directly analyzes post-PCR product and is also used for oligonucleotide purification and analysis. It can also be used for total RNA purification and quantitation.

Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

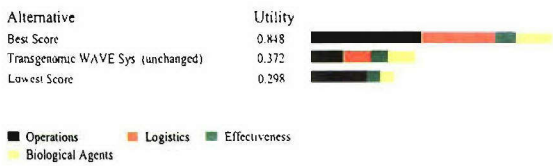
Transgenomic WAVE System ranked in the bottom third of all evaluated products for analytical laboratories and earned 51% of the utility points of the best score.

Diagnostic Laboratory Ranking

Preference Set = Diagnostic Laboratory

Transgenomic WAVE System ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 59% of the utility points of the best score.

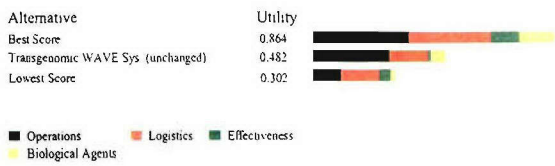
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Transgenomic WAVE System ranked in the bottom third of all evaluated products for mobile laboratories and earned 44% of the utility points of the best score.

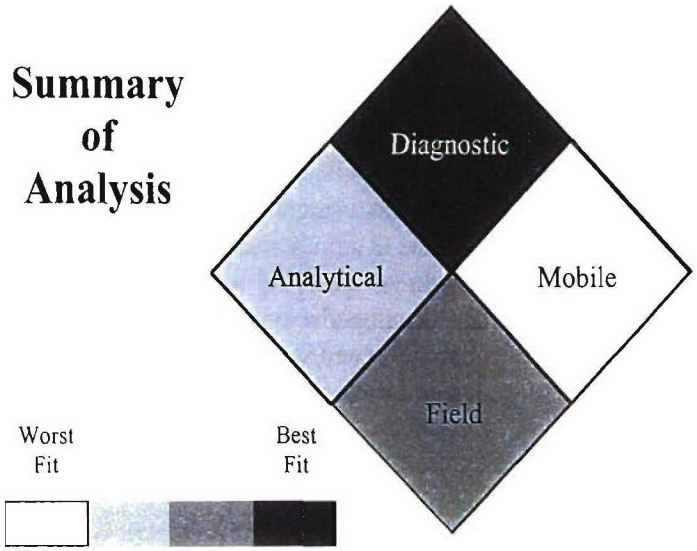
Field Use Ranking



Preference Set = Field Use

Transgenomic WAVE System ranked in the bottom third of all evaluated products for field use and earned 56% of the utility points of the best score.

Summary of Analysis



Transgenomic WAVE System Evaluation Criteria Provided by Vendor

Sensitivity:
- Unknown CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System sometimes able to interpret raw data or call a positive through internal software
- Assay available and capable of detecting two or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

System requirements:
- System or device has 110V and 220V electrical requirement
- The system or device requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less after performing PCR on the sample
- 384 samples/batch or higher
- Less than 10 ul volume needed per test for detection
- The system or device is currently fully automated

Training/Speed/Manpower:
- More than a day of training
- Greater than 20 minutes required for set-up
- 3-5 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 4 solutions or buffers used
- 1 components
- No cleaning required

Maintenance:
- 3 consumables or expendables needed
- Every six months service required
- Expected life is greater than 10 years
- 10 -20 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- More than 50 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated at 25°C only
- Components must be stored at 4°C and room temperature
- Device or system has peak performance at normal relative humidity conditions only

Cost: $0.45-0.57/sample (post PCR)
$49,950.00-90,000.00/system or device (excluding reagents)

Transgenomic
12325 Emmet St.
Omaha, NE 68164
www.transgenomic.com

Point of Contact: Will Jeffers
(410) 992-1690 Cell. (410) 598-7885
fax. (410) 992-3861
wjeffers@transgenomic.com

Triage Meter

by Biosite

Description: The Triage meter consists of a microfluidic immunoassay protein chip (ticket) and a portable fluorometer to read the ticket. Triage measures multiple analytes simultaneously in any biological fluid using a single ticket, which makes it possible to simultaneously identifying all BW threat agents on one ticket. Biosite has also developed a highly specific (low false alarm rate) and sensitive immunoassay on Triage for the detection of *Bacillus anthracis*.

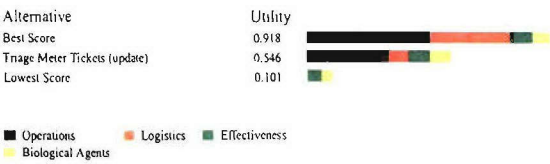
Technology:

	Triage
Assay Time	15min
Sensitivity	1 picomolar (pM) of analyte
Sample volume	250 microliter (ul)
Power consumption	1 Watt (W)
Meter (fluorometer) Size	6x8x3"
Ticket Size	1.5x4x0.2"

Able to Detect the Following Organism:
Bacillus anthracis (4)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

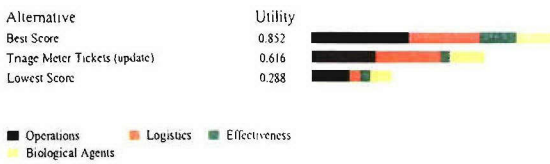
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

Triage Meter ranked in the middle third of all evaluated products for analytical laboratories and earned 59% of the utility points of the best score.

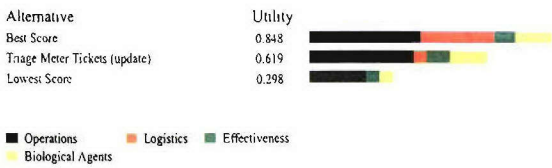
Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

Triage Meter ranked in the middle third of all evaluated products for diagnostic laboratories and earned 72% of the utility points of the best score.

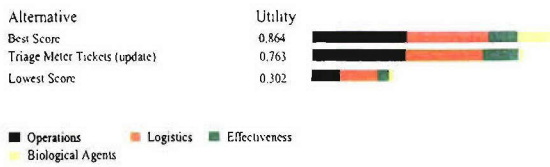
Mobile Laboratory Ranking



Preference Set = Mobile Laboratory

Triage Meter ranked in the middle third of all evaluated products for mobile laboratories and earned 73% of the utility points of the best score.

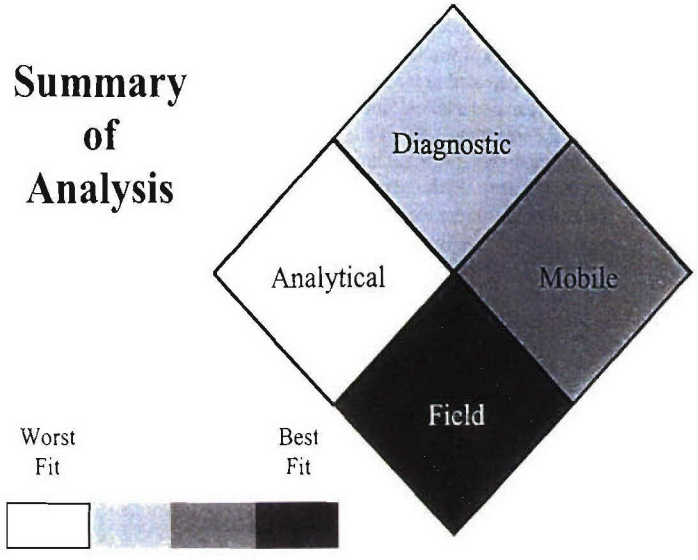
Field Use Ranking



Preference Set = Field Use

Triage Meter ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

Summary of Analysis



Triage Meter Evaluation Criteria Provided by Vendor

Sensitivity:
- 100-1,000 CFU per ml

Maturity Gauge:
- Is commercially available

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- No additional pieces of equipment needed

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 32 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 minutes required for set-up
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for single use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- Less than once a year service required
- Expected life is 3-5 years
- Less than 5 minutes required for daily assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 6 months and 1 year

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $25.00/sample
$25.00/system or device, Approx. $4500.00 for reader

Biosite Inc.
11030 Roselle St.
San Diego, CA 92121
www.biosite.com

Point of Contact: Ferran Prat
(858) 597-4815 ext. 3181
discovery@biosite.com

Upconverting Phosphor Technology (UPT) Handheld Sensor

by SRI International

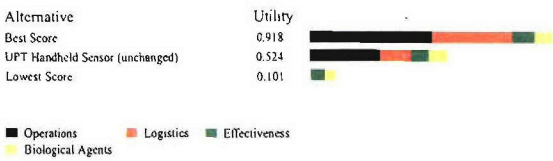
Description: The fieldable handheld biosensor is designed to sensitively detect the presence of low-levels of biological warfare agents in a variety of military operational environments. The system is depicted in the Figure and consists of several subsystems and disposable items. The system uses a lateral flow immunoassay test strip with upconverting phosphor technology (UPT) reporters. Sample collection is performed using the included surface sampling kit. Alternatively, if the unknown sample is already in liquid form, it may be directly applied to the test strip. Each lateral flow test strip is capable of screening the liquid sample for one to three different biological targets (e.g. toxins, viruses, and bacteria). Following an incubation period of at least 15 minutes, the sensor analyzes the assay test strip. This is accomplished by sliding the reader cover door open, inserting the test strip into the slot, and initiating the scan using the Palm touch screen display. The strip is analyzed in about 45 seconds and the results are displayed on the reader screen and stored in the appropriate data file.

Able to Detect the Following Organisms/Toxin:
Bacillus anthracis (1)
Orthopox virus (1)
MS-2 bacteriophage (1)
Ricin (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: The fieldable handheld biosensor is based on a new technology for sensitive detection of biological materials, known as the Upconverting Phosphor Technology (UPT). Upconverting phosphors are rare-earth doped ceramic materials with the unique property of emitting visible light upon excitation with near-infrared light . Known since 1966, SRI (under DARPA funding) has developed UPT for the sensitive detection of biological targets (e.g., bacteria, viruses, and toxins) in solution. The ability to perform highly multiplexed (i.e., multiple target) assays on a single sample is the first key advantage of UPT™ over conventional reporters such as molecular fluorescent dyes, colloidal gold and fluorescent microspheres. The second major advantage is that, due to the unique nature of the upconversion process itself—no other materials in nature upconvert—there is no optical background. Consequently, these materials can be detected in dirty environmental samples. Third, because single phosphor particles are detected using diode laser excitation sources and conventional optical systems, compact biosensors are possible that offer exquisite sensitivity. Finally, since their emission properties are a characteristic of the bulk ceramic material, the upconverting phosphors are photochemically stable with long lifetimes (years). Hence, the upconverting phosphors are ideal reporters for use in the field for sensitive, real-time detection and identification of pathogens with minimum false alarms. Furthermore, their stability means that UPT-based assays can be archived (and stored in a dry condition) for later analysis.

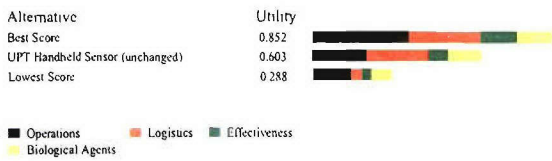
Analytical Laboratory Ranking



Preference Set – Analytical Laboratory

Upconverting Phosphor Technology Handheld Sensor ranked in the bottom third of all evaluated products for analytical laboratories and earned 57% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set – Diagnostic Laboratory

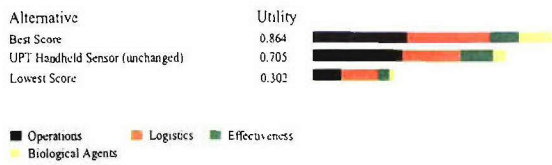
Upconverting Phosphor Technology Handheld Sensor ranked in the middle third of all evaluated products for diagnostic laboratories and earned 71% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set – Mobile Laboratory

Upconverting Phosphor Technology Handheld Sensor ranked in the middle third of all evaluated products for mobile laboratories and earned 69% of the utility points of the best score.

Field Use Ranking

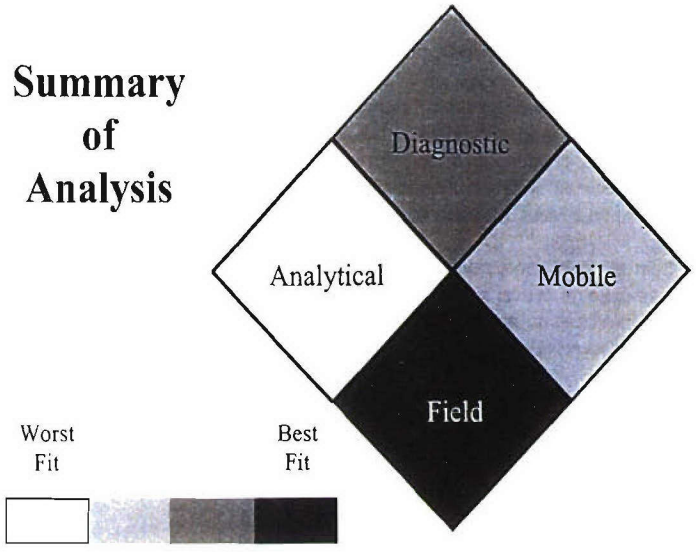


Preference Set – Field Use

Upconverting Phosphor Technology Handheld Sensor ranked in the middle third of all evaluated products for field use and earned 82% of the utility points of the best score.

Upconverting Phosphor Technology (UPT) Handheld Sensor Evaluation Criteria Provided by Vendor

Summary of Analysis



Sensitivity:
- 1,000-10,000 CFU per ml

Maturity Gauge:
- A few devices or systems exist (brass board)

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- There are no shaking or vortexing steps
- System always able to interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- One additional piece of equipment needed

System requirements:
- System or device uses batteries
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 2 samples/batch or higher
- Less than 250 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is intended for multiple use
- 0-1 solution or buffer used
- 2 components
- No cleaning required

Maintenance:
- 2 consumables or expendables needed
- Once a year service required
- Expected life is 3-5 years
- No required daily quality assurance procedures

Transportation:
- Approximately the size of a toaster
- Between 1 and 5 kg
- Shelf life between 1 and 3 years

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $10.00/sample
$25,000.00/system or device

SRI International
333 Ravenswood Ave., Room 30626
Menlo Park, CA 94025
www.sri.com

Point of Contact: David E. Cooper
(650) 859-3742
fax. (650) 859-5036
david.cooper@sri.com

Verigene ID Assay System

by Nanosphere, Inc.

Scheme 2 Verigene™ ID

Description: The Verigene platform is a universal molecular testing system that transcends the limitations of existing technologies. Verigene's superior performance is based on ClearRead™ technology that uses proprietary and patented nanoparticle probes to identify DNA, RNA and protein targets. This technology directly detects a target without amplification of nucleic acid, eliminating the variability associated with the amplification process (PCR). ClearRead™ also permits the simultaneous identification of multiple targets from a single sample. Nanosphere's Verigene™ ID is a stand-alone instrument designed to read light scatter from the gold nanoparticles. The device illuminates the test slide and uses inexpensive optics to deliver scattered light from the test sites to a photosensor. This detector is interfaced to an embedded microprocessor that allows automatic spot detection and data processing.

No Formal Detection Assay Available

Technology: For the detection of specific BWAs with gold probes, target-specific oligonucleotides are conjugated to gold nanoparticles at a very high density by using proprietary methods. The high density of oligonucleotides attached to the probe confers stability toward salt and temperature fluctuations, provides low non-specific binding to surfaces and has a significant impact on assay sensitivity and specificity. The chip-based detection assay is primarily a sandwich hybridization where the target is captured between surface-immobilized capture strands and the nanoparticle probe. The assay design requires that for detection to occur, both the capture and the probe bind the target. Therefore, assay specificity is derived from both the capture strand and the probe. Detection is achieved by a signal enhancement procedure that involves depositing a signal enhancement reagent at the test site in a strictly gold-dependent manner and measuring light scatter from the resulting enhanced gold nanoparticles. The enhancement step provides greater than 10^5-fold signal enhancement.

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
Verigene ID (new)	0.260
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

Verigene ID ranked in the bottom third of all evaluated products for analytical laboratories and earned 28% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
Verigene ID (new)	0.295
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

Verigene ID ranked in the bottom third of all evaluated products for diagnostic laboratories and earned 35% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
Verigene ID (new)	0.417
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

Verigene ID ranked in the bottom third of all evaluated products for mobile laboratories and earned 49% of the utility points of the best score.

Field Use Ranking

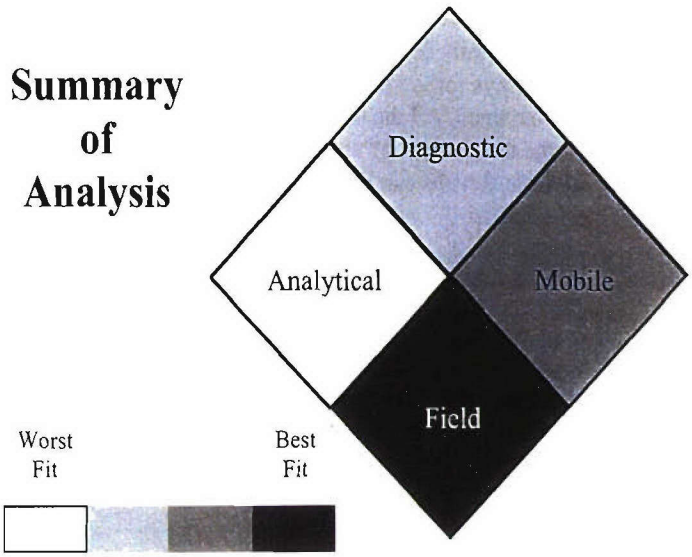
Alternative	Utility
Best Score	0.864
Verigene ID (new)	0.474
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

Verigene ID ranked in the bottom third of all evaluated products for field use and earned 55% of the utility points of the best score.

Summary of Analysis



Verigene ID Assay System

Evaluation Criteria Provided by Vendor

Sensitivity:
- CFU per ml unknown

Maturity Gauge:
- Expected to be ready for commercialization within one calendar year
- A few systems or devices exist (brass board)

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 50-60 min
- 2 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could be adapted into a fully automated system with some effort

Training/Speed/Manpower:
- An afternoon of training
- Less than 5 min required for set-up
- 9-12 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- More than 4 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- 5 or more consumable or expendable needed
- Needs service less than once a year
- Expected life measure of greater than 10 years
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a toaster
- Between 1-5 kg
- Shelf life between 6 months and 1 year

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- Number of shaking or vortexing steps is unknown
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting two or more biological agents or toxins within the same test
- Unknown number of additional equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components must be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $ To Be Determined/sample
$ To Be Determined/device or system

Nanosphere, Inc.
4088 Commercial Ave
Northbrook, IL 60062
www.nanosphere.us

Point of Contact: William Cork
(847) 400-9112
(847) 400-9199 fax
wcork@nanosphere.us

VIP for EHEC

by BioControl Systems, Inc.

Description: VIP family of rapid tests are patented, lateral flow immunoprecipitate assays for the detection of food pathogens. Each VIP test is totally self-contained. All the reagents have been systematically incorporated into the test device. After sample enrichment simply inoculate the VIP test. Results can be read after 10-20 minutes of room temperature incubation.

VIP tests are available for the detection of

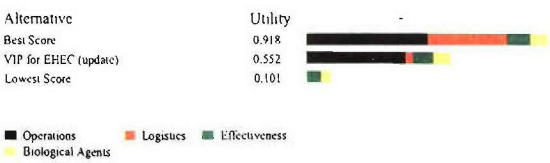
- *Salmonella*, AOAC Official Method 999.09
- *Listeria*, AOAC Official Method 997.03
  - Official Method extended to include environmental samples
- *E. coli* O157:H7, AOAC Official Method 996.09

Able to Detect the Following Organism:
E. coli 0157:H7 (2)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: Proprietary antibodies, with high specificity to *E. coli* O157:H7 antigens, are bound to chromogenic carrier and, separately, to solid support matrix. Reagents are incorporated in test units and produce visually discernible reaction product in presence of *E. coli* O157:H7. During initial hydration of test unit, *E. coli* O157:H7 reacts with antibody-chromogen complex to form antigen-antibody chromogen complex, which flows across lateral flow membrane and is bound by antibody immobilized on membrane. Positive reaction is indicated by presence of detection line positioned across the solid support in test sample window. Proper test completion is indicated by another line formed in test verification window. Absence of line in test verification window invalidates the test.

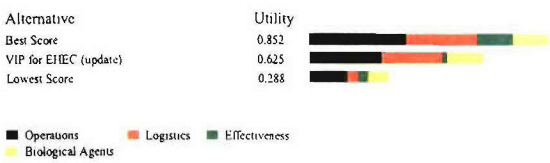
Analytical Laboratory Ranking



Preference Set = Analytical Laboratory

VIP for EHEC ranked in the middle third of all evaluated products for analytical laboratories and earned 60% of the utility points of the best score.

Diagnostic Laboratory Ranking



Preference Set = Diagnostic Laboratory

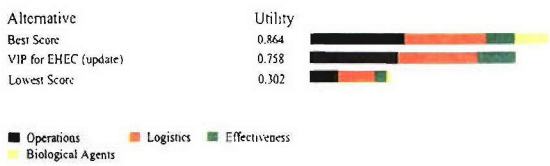
VIP for EHEC ranked in the middle third of all evaluated products for diagnostic laboratories and earned 73% of the utility points of the best score.

Mobile Laboratory Ranking

Preference Set = Mobile Laboratory

VIP for EHEC ranked in the middle third of all evaluated products for mobile laboratories and earned 75% of the utility points of the best score.

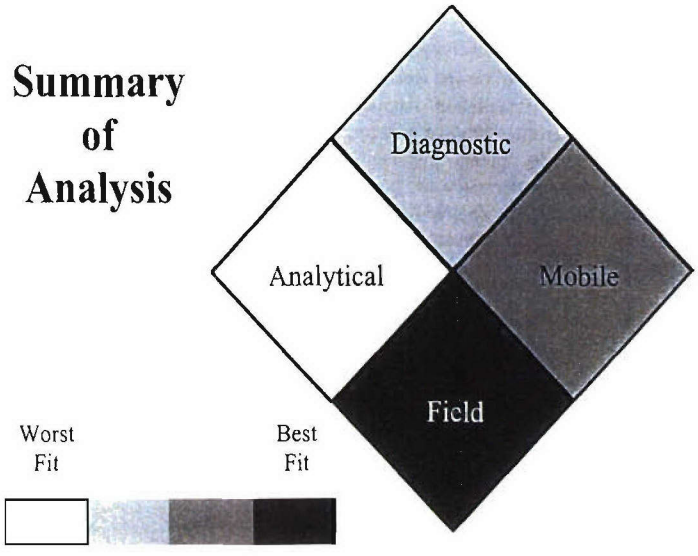
Field Use Ranking



Preference Set = Field Use

VIP for EHEC ranked in the top third of all evaluated products for field use and earned 88% of the utility points of the best score.

Summary of Analysis



VIP for EHEC Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- No electrical requirement
- The system or device does not require water
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection 20 minutes or less
- 1 sample/batch
- Less than 100 ul volume needed per test for detection
- The system or device is not amendable to automation

Training/Speed/Manpower:
- Very brief training
- No set-up required
- 0-2 manual steps required for detection

Re-use:
- Device or system is designed for single use
- 0-1 solution or buffer used
- 1 component
- No cleaning required

Maintenance:
- 0-1 consumable or expendable needed
- No service required
- NA expected life
- No daily quality assurance procedures required

Transportation:
- Approximately the size of a soda can
- Less than 1 kg
- Shelf life between 1 and 3 years

Ease of use/Utility
- Can view results "in real time"
- No centrifugation steps
- No shaking or vortexing steps
- System not able to interpret raw data or call a positive through internal software
- Not capable of detecting multiple biological agents or toxins within the same test
- No additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Less than 200 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at room temperature
- Performance of the device or system is not influenced by relative humidity

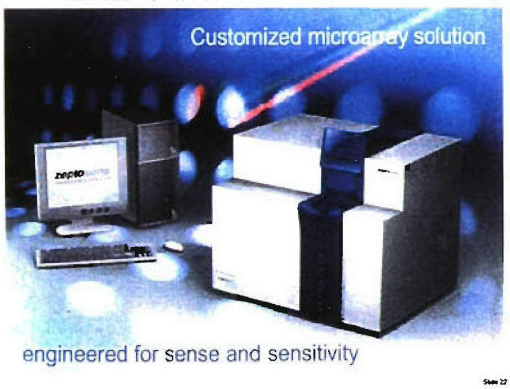
Cost: $7.00-10.00/sample
$6.00-8.00/system or device

BioControl Systems, Inc.
12822 SE 32nd St.
Bellevue, WA 98055
www.biocontrolsys.com

Point of Contact: Maritta Ko
(425) 603-1123 ext. 105
fax. (425) 603-0070
mko@biocontrolsys.com

ZeptoMARK and SensiChip Product Line

by Zeptosens AG



Description: High sensitivity DNA and Protein microarray system comprehending sample isolation and workup, assay performance, readout of results, data collection and data presentation. Applicability has been shown for determination of gene expression as a consequence of infection, medical treatment, cancer progression, stress, ageing. Applicability has been shown as well for the determination of protein expression and protein activation in drug development. System has been successfully applied for the high sensitivity determination and characterization of clinically relevant pathogenic bacteria with minimal sample preparation requirements.

Able to Detect the Following Organisms/Toxins:
Corynebacterium diptheria (1)

(1) Assay Developed
(2) Assay Validated
(3) Commercially Available as Wet/Frozen Reagent
(4) Commercially Available as a Freeze-Dried Reagent

Technology: In contrast to competing microarray readout systems based on epifluorescence Zeptosens is using planar waveguide detection. This results in facilitated sample workup requirements (more tolerant towards contamination) and about 50 fold increase of sensitivity. Lowest limit of detection: 1 attomol labeled DNA

Minimum amounts of sample:

without amplification: 1 µg total RNA
with linear enzymatic amplification: 10 ng total RNA
without enzymatic amplification but mathematical treatment of the results: 20 ng total RNA

Analytical Laboratory Ranking

Alternative	Utility
Best Score	0.918
ZeptoMARK and SensiChip (new)	0.661
Lowest Score	0.101

Operations Logistics Effectiveness Biological Agents

Preference Set = Analytical Laboratory

ZeptoMARK ranked in the middle third of all evaluated products for analytical laboratories and earned 72% of the utility points of the best score.

Diagnostic Laboratory Ranking

Alternative	Utility
Best Score	0.852
ZeptoMARK and SensiChip (new)	0.592
Lowest Score	0.288

Operations Logistics Effectiveness Biological Agents

Preference Set = Diagnostic Laboratory

ZeptoMARK ranked in the middle third of all evaluated products for diagnostic laboratories and earned 69% of the utility points of the best score.

Mobile Laboratory Ranking

Alternative	Utility
Best Score	0.848
ZeptoMARK and SensiChip (new)	0.373
Lowest Score	0.298

Operations Logistics Effectiveness Biological Agents

Preference Set = Mobile Laboratory

ZeptoMARK ranked in the bottom third of all evaluated products for mobile laboratories and earned 44% of the utility points of the best score.

Field Use Ranking

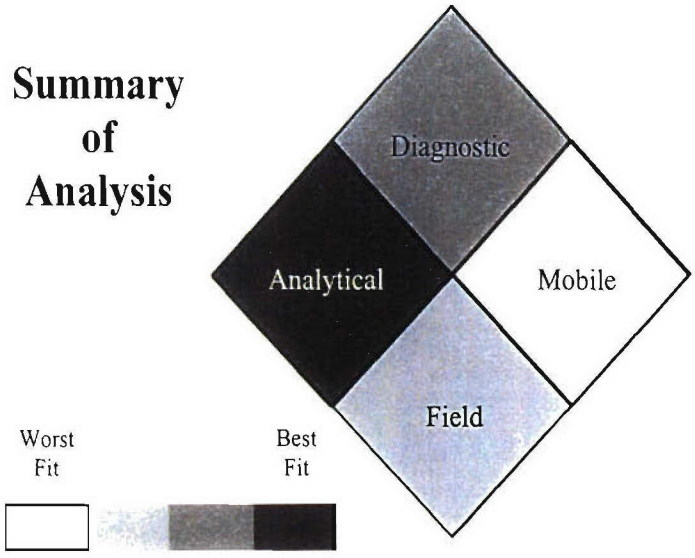
Alternative	Utility
Best Score	0.864
ZeptoMARK and SensiChip	0.430
Lowest Score	0.302

Operations Logistics Effectiveness Biological Agents

Preference Set = Field Use

ZeptoMARK ranked in the bottom third of all evaluated products for field use and earned 50% of the utility points of the best score.

Summary of Analysis



ZeptoMARK and SensiChip Product Line

Evaluation Criteria Provided by Vendor

Sensitivity:
- 1-100 CFU per ml

Maturity Gauge:
- Is commercially available

System requirements:
- System or device has 110V electrical requirement
- The system or device does not requires water aliquots
- The system or device does not require an external air or gas source
- The system or device does not require an external vacuum source

Throughput of product:
- Single sample detection in 60 min or more
- 384 samples/batch or higher
- Less than 50 ul volume needed per test for detection
- The system or device could easily be adapted into a fully automated system

Training/Speed/Manpower:
- A day of training
- Greater than 20 min required for set-up
- 6-8 manual steps required for detection

Re-use:
- Device or system is intended for multiple detections
- 4 solution or buffer used
- 5 or more components
- No cleaning required, uses disposable cartridges

Maintenance:
- 4 consumable or expendable needed
- Needs service every 6 months
- Expected life measure of 5-10 years
- Less than 5 minutes required for daily quality assurance procedures

Transportation:
- Approximately the size of a home dishwasher
- Between 25-50 kg
- Shelf life between 1-6 months

Ease of use/Utility
- Cannot view results "in real time"
- No centrifugation steps
- A single shaking or vortexing steps
- System can interpret raw data or call a positive through internal software
- Assay not available, but capable of detecting four or more biological agents or toxins within the same test
- Three additional pieces of equipment needed

Signature:
- No sounds produced that cannot be deactivated
- Greater than 500 BTUS generated

Operational conditions:
- Operated from 15°C to 37°C
- Components can be stored at 4°C
- Performance of the device or system is not influenced by relative humidity

Cost: $800/sample
$130,000/device or system

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