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UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

PERIODONTAL STAIN TEST DIAGNOSIS PROGRAM

1989

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Samples to be sent to:

Peggy E. Yates
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CB #7455
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Chapel Hill, NC 27599

SAMPLING KIT CONTENTS

Tuberculin syringes
(B-D 5602)
Special
disposable plastic needles
Sterile saline, isotonic
(Snap-cap vial)
Forceps
Paper points, coarse
(Mynol No. 518)
pH paper
(pHydrion Vivid 1-11)
Coverslips
(No. 1 1/2, 22mm square)
Manilla coin envelopes
Forms

Statement A per telecon Chris Eisemann
NMRDC/Code 04A
Bethesda, MD 20814-5044

NWW 3/5/92

USE OF CREVICULAR FLUID AND SUBGINGIVAL PLAQUE SAMPLING KIT

1. Determine patient periodontal status. See Periodontal Assessment, page 5.

   --use the Löe and Silness Gingival Index (page 6). Each gingival unit (i.e. the lingual, buccal, mesial, and distal aspects) of the individual tooth is scored after gentle probing. The criteria is stated on an attached sheet.

2. Have consent form (page 7) signed by patient.

3. Prepare syringe (1.00 cc disposable syringe),

   --draw up 0.1 cc of sterile isotonic solution.

4. Set out coverslips.

5. Isolate area to be sampled (anterior site)

   --saliva ejector on the lingual
   --cotton rolls in the buccal vestibule and lingual if necessary to control moisture
   --remove and discard supragingival plaque

6. Dry and clear the area to be sampled of all debris by lightly dabbing with sterile gauze.

   --<u>never</u> blow air onto the sampling site

7. Place the tip of the syringe at the area to be sampled.

   --<u>never</u> actually contact the papilla

8. Slowly inject and reaspirate the solution into the crevice between the tooth and papilla

   --inject and reaspirate 3 to 4 times into the same area
   --this should take approximately 10-15 seconds

9. Place one small drop of the solution sample on a single coverslip. Lay a second coverslip over the drop and slowly slide the coverslips apart to evenly distribute the sample. Lay both coverslips face up to dry. Repeat 3 or 4 times or until all of the aspirate is used.

10. Repeat procedures 5-9 above for a posterior site.

11. With a periodontal probe or explorer remove a sample of subgingival plaque. Distribute this material to several coverslips and spread as evenly as possible in the same way as the crevicular fluid.

12. As soon as all coverslips are thoroughly dry, they must be placed in manilla coin evelopes marked with the patients' names and sampling sites. The envelopes should be sent to the address on the cover page immediately. If this is not possible, the samples should be refrigerated.

13. Fill in Patient and Specimen Information sheet, page 9.

PERIODONTAL ASSESSMENT

AAP Classification

Type	Code	Diagnosis
N	-	HEALTHY: No bleeding upon probing: No pockets in excess of 3 mm.
I	04500	GINGIVITIS: Inflammation of the gingiva characterized by changes in color, form position, texture: Bleeding Index >20%: Periodontal pocket depths 3-4 mm range: No bone loss.
II	04600	EARLY PERIODONTITIS: Pocket depths in 4 mm range with slight loss of connective tissue attachment and minimal horizontal bone loss: BI may be > 20%.
III	04700	MODERATE PERIODONTITIS: Pocket depths in 4-7 mm range: 2-4 mm irregular bone loss, slight increase in mobility: early furcation involvement: BI may be elevated > 20%.
IV	04800	ADVANCED PERIODONTITIS: Pockets > 7 mm. Major bone loss, increased tooth mobility severe furcation involvement; possible extractions; BI may be elevated > 20%.
RPP	04900	REFRACTORY PROGRESSIVE PERIODONTITIS: Rapid bone and attachment loss; resistance to normal therapy and usually associated with gingival inflammation and continued pocket formation.
JP		JUVENILE PERIODONTITIS: A localized or generalized inflammatory loss of attachment and bone in adolescents; lesions are often associated with incisors and first molars; no evidence of systemic disease.

RISK FACTORS: When determining susceptibility to periodontal disease, patients in the previous classifications should be considered high risk patients if any of the following factors are also present:

1. Repeatedly high plaque scores at each evaluation: (PI >20%)
2. Persistent high bleeding index with probing after initial therapy: (BI >20%).
3. Previous history of definitive periodontal therapy
4. Age of the patient: Young patients with advanced disease may be more susceptible.
5. Multiple tooth replacements and restorations

LÖE AND SILNESS GINGIVAL INDEX

Index	Description
0	Normal gingiva. Gingiva is pink or pale in color. On palpation, the gingiva should be firm.
1	Mild inflammation. Gingival margin is slightly more reddish or bluish than normal. Bleeding is not provoked when tissues are probed by running the probe along the soft tissue wall of the sulcular orifice.
2	Moderate inflammation. The gingiva exhibits redness, edema, and glazing. There is enlargement of the margin due to edema. Bleeding is provoked by probing in the presence of either mild or moderate inflammation.
3	Severe inflammation. The gingiva is markedly red or reddish blue and enlarged. There is ulceration or a tendency to spontaneous bleeding (e.g. after the use of air).

Score each area (lingual, facial, mesial, distal) of the gingival unit with one of the above numbers. Add up the four numbers and divide this total number by four. This gives us the gingival index for this particular tooth.

In this study, a gingival index number is needed for each adjacent tooth of the papilla being sampled.

CONSENT FORM

Study of Samples of Crevicular Fluid

You are being asked to participate in a research project being conducted under the auspices of the University of North Carolina School of Dentistry to evaluate new staining procedures for white blood cells and bacteria in the crevice between the tooth and gum. The following information is provided so that you can make an informed decision about your willingness to participate.

1. Explanation of the procedures to be used in this project:

a. A routine clinical evaluation of the condition of the gums, teeth and other tissues of the mouth.

b. After removing the supragingival plaque and drying the tooth and gums a very small amount of sterile saline will be applied to the cervice between the gum and tooth by means of a very fine teflon tube. The fluid is drawn back into the tube and is transferred to a plate of glass for staining and examination under a microscope.

c. Samples of accumulated subgingival plaque obtained during routine non-invasive examination will be transferred to glass coverslips for staining and examination under a microscope.

2. The procedures are noninvasive (do not penetrate tissue barriers) and the aspiration of the tissue fluid should cause no pain.

3. You (your child) will benefit by having an additional diagnostic procedure which will help in selecting the appropriate treatment if there is a gum problem.

4. This study does not offer treatment. If the results of this test indicate that therapy will be of benefit to the patient, he or she will be referred to a periodontist for further evaluation and/or treatment.

5. The opportunity to obtain more information on the procedures being used in this study has been provided. I am satisfied with the explanations provided.

6. I understand that I am free to withdraw my consent and to discontinue participation in the project at any time and that doing so will not affect my opportunity to obtain dental treatment in the School of Dentistry.

7. I understand that the procedures which have been explained to me were reviewed by the School of Dentistry Committee on Investigations Involving Human Subjects and that, if I should wish so, I may contact the Committee through its Chairman, Room 101, Dental Research Center, telephone number 966-1538.

8. If you have any further questions about this project or your participation in it, you may contact Peggy Yates or Dr. J.S. Hanker at (919) 966-4593 or Dr. E.J. Burkes, Jr. at (919) 966-2746.

9. I understand that all records will be kept confidential and that I will not be identified in any reports or publications.

Having read each of these statements, I agree to participate in this clinical research project at the Dental Research Center, School of Dentistry, University of North Carolina.

_____
Patient's Signature

_____
Date

_____ _____
Witness' Signature Chart Number

_____ _____
Date Responsible Investigator

Having read each of these statements, I agree to have my child _____ participate in this clinical research project at the Dental Research Center, School of Dentistry, University of North Carolina.

_____
Parent or Guardian Signature

_____ _____
Witness' Signature Date

_____ _____
Date Responsible Investigator

Patient Information

Date: _____

Patient's Name _____
(please print)

Chart Number: _____

Age: _____

Clinician: _____

AAP Classification _____

Specimen Information

Tooth No. and Surface	Time Since Last Treatment	Plaque Index	Remove Supragingival Plaque	Pocket pH	Crevicular Fluid	Pocket Depths	Bleeding on Probing	Gingival Index	Subgingival Plaque	Subgingival Culture*	Tooth Mobility

*To be done locally, if desired.