INSTRUCTIONS FOR USE AND STORAGE OF LIVE ANTI-PLAGUE DRY VACCINE

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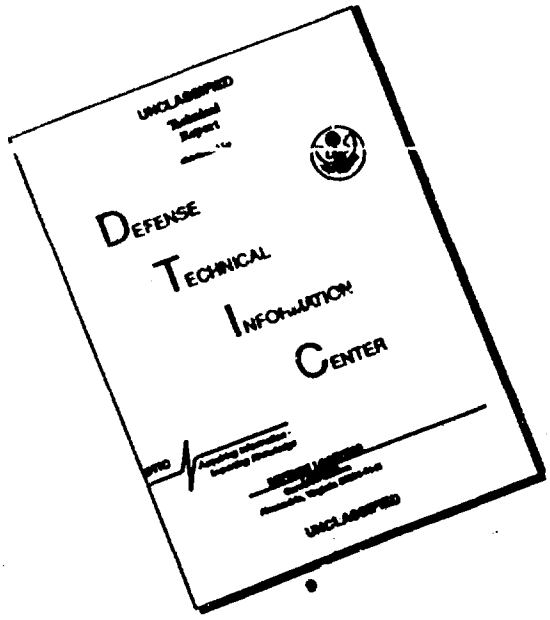

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INSTRUCTIONS FOR USE AND STORAGE OF LIVE ANTI-PLAGUE DRY VACCINE

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Label on Vaccine [illegible]

USSR MINISTRY OF HEALTH

"Mikrob," Institute for Microbiology and Epidemiology of the Southeastern USSR

Dry, live anti-plague vaccine 1, 17 [1]

In the box _____ ampules In the ampule _____ doses

Dilution: for intracutaneous use with ___ cm^3 physiological salt solution
for exterior use with ___ cm^3 of physiological salt solution
for hypodermic use with ___ cm^3 of physiological salt solution

To be stored in a dark room at a temperature not above +4°C

Series No..... Control No..... Usable until.....19

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1) Stamped on

INSTRUCTIONS FOR USE AND STORAGE OF
LIVE, DRY ANTI-PLAGUE VACCINE

1) Live, dry anti-plague vaccine is a suspension of live bacteria vaccine strains of the plague bacterium dried in a saccharose gelatin.

2) Live, dry anti-plague vaccine builds up active immunity, lasting up to one year. When annual inoculations of population groups are carried out, revaccination takes place after 12 months.

Under especially difficult epidemiological conditions, revaccination is carried out after six months, preferably twice.

In places where inoculations are given for the first time, or after a delay of some years, double vaccination should be done so that a basic immunity may be established. In double inoculation, the interval between the first and the second inoculations should be 20 to 25 days. The dose for the second inoculation should be the same as for the first.

3) The vaccine should be stored in a room where the temperature is not above +4°C. (It can also be stored under refrigeration, if it is not exposed to repeated thawing and freezing). Under these conditions, the vaccine can be stored for six months. After six months of storage, the vaccine is again checked by the institute which produced it and, if found usable, is used in accordance with instructions, by the authorities which carry out the inoculations with the vaccine series in question.

Installations unable to provide storage at the proper temperature are prohibited from keeping vaccine supplies for a longer period than 10 to 15 days.

4) Counterindications for inoculations are acute diseases of the heart, uncompensated heart defects, severe chronic diseases of liver, kidneys, and other internal organs, active forms of tuberculosis, severe cases of hypertony and arteriosclerosis, cachexia, severe cases of furunculosis, diabetes, and the second half of pregnancy.

For chronic malaria cases, administration of acridin or quinine prior to the inoculation is recommended. Persons suffering from acute infectious diseases and those whose body temperature is high should be inoculated when they have recovered and are able to work.

5) Dry, live multiplying vaccine may be applied intracutaneously, percutaneously, or subcutaneously, and is produced in separate series of sealed ampules. Each series may be used for intracutaneous, percutaneous, or subcutaneous inoculations, depending upon the method of dilution.

6) When inoculation is carried out, the following should be taken into consideration:

a) For increased immunity, intracutaneous inoculation is to be preferred to subcutaneous inoculation, with percutaneous next in the order of preference. Hence, healthy population groups in the seven to 70 age range showing no counterindications are inoculated intracutaneously. Children under seven, women in the first half of the pregnancy period, and nursing children are inoculated percutaneously due to the lessened reaction to this method. During a complicated epidemiological situation, persons with relative counterindications are also inoculated percutaneously, namely those who are weakened by previous illness and those who have mild forms of the chronic illnesses listed above. Persons of advanced age (over 60) may be inoculated intracutaneously or percutaneously, according to the medical indications. Children under the age of two years are exempt from inoculation.

7) The ampules and their content are to be thoroughly checked before and after the dilution. If there are cracks, foreign matter, unbroken lumps, or uneven suspension present, the vaccine should be discarded. The vaccine should be diluted immediately prior to the inoculation. Vaccine which has been diluted but not used within four hours is destroyed through boiling or the addition of a sterilization liquid. All handling of the vaccine as well as its application should be done with observation of all sterilization rules. Before the dilution the person who carries it out should wash his hands with soap and rub them with alcohol. The ampule and the file are also wiped with alcohol. The upper part of the neck of the ampule is filed, wiped with alcohol and very carefully flamed, so that the ampule body is not heated. The...

the neck of the ampule is broken and a sterile physiological salt solution in the amount required for the vaccination method in question is introduced into the ampule by means of a boiled syringe (see points 8, 11 and 14.) The opening in the ampule is temporarily covered with a sterile piece of cotton and the contents shaken, whereupon it is held in the hand for three to five minutes to warm it slightly and it is shaken once more until the dry vaccine is transformed into an even suspension. The obtained bacterial suspension is withdrawn from the ampule by means of a sterile pipette or syringe with a long cannula, and is transferred to a bottle containing the amount of physiological salt solution required for dilution of the vaccine.

8) The volume of physiological salt solution in which the vaccine must be diluted for intracutaneous inoculation is given on each ampule and on the label of the box. First, 1 to 3 cm^3 of physiological salt solution is added to the ampule, and when the vaccine is completely dissolved, it is transferred, as described above, to the bottle containing the volume of physiological salt solution called for on the box label or on the ampule. An allowance should be made for the volume of salt solution introduced into the ampule to dissolve the vaccine.

After such dilution, one dose for intracutaneous inoculation of persons over the age of 14 is .2 cm^3.

For inoculation of children under 14 years the vaccine is diluted with twice the amount of physiological salt solution called for on the label, which gives a dose of .15 cm^3 for children 7 to 10 years of age, and .2 cm^3 for children 10 to 14 years of age.

9) When the vaccine has been diluted for intracutaneous inoculation in accordance with the above, the injection is done, with all the rules of asepsis observed, strictly intracutaneously, preferably in the upper one-third of the shoulder, or in the upper part of the inside of the left arm.

The appearance of a whitish condensed blister ("lemon peel") at the place of vaccination indicates a correctly carried out inoculation. Cannulas and syringes are to be sterilized before all inoculations only by means of boiling.

10) One local and one general reaction can be observed in vaccinated persons:

a) The local reaction appears in almost all cases, in the form of swelling, reddening, condensation (constriction), and pain at the place of vaccination. Inoculations are often followed by a disturbance in the regional lymph glands and pain when they are touched, or tenderness in the armpit may be experienced, without a visible disturbance of the lymph glands. A papilla may form on the place of injection, which turns into a pustule. The pustule most often dissolves through the formation of a scab three to five days after the inoculation. All local symptoms begin to form 8-10-14 hours after the inoculation, reach full development toward the end of the first or the beginning of the second day, and gradually disappear after three to five days (more seldom after seven to eight days.)

b) The general reaction shows up in indisposition, chills, headaches, and fever, most often up to 37.5°C, less frequently up to 38°C, and very rarely up to 39°C. On occasion, nausea and vomiting occur. The general reaction appears during the first days, and disappears after one to two days. The general reaction fails to appear in some of those inoculated.

11) The amount of physiological salt solution required for dilution for percutaneous inoculation is given on the label of the box containing the vaccine. At such dilution, the dose for persons over 10 years of age is .15 cm^3 (three drops from an eye pipette), for children from seven to ten .10 cm^3 (two drops), and for children between two and seven years .05 cm^3 (one drop). The vaccine diluted for percutaneous inoculation is left in the ampule.

12) Percutaneous inoculation against plague is done on the inside of the lower arm, or on the outside of the upper third of the shoulder, in the following manner:

The skin at the spot selected is carefully rubbed with a piece of cotton moistened with alcohol. The alcohol is let dry, whereupon the outer epidermic layer (horny layer) is lightly scraped with a sterile vaccination point or Huberts lancet, in three areas of the disinfected skin in the case of childre over 10 and adults, in two areas in

children seven to 10, and in one area in children two to seven. The scraping is stopped as soon as the area reddens. Production of a much moistened area should not be strived for. The area should be 1½ to 2 cm^2, and the distance between areas should be 2 to 3 cm. To the area prepared in this manner, drops of vaccine are added, whereupon eight scratches are made, as in smallpox vaccination, four lengthwise and four crosswise of the vaccine drops. The vaccine is carefully rubbed in over the entire surface of the prepared spot, let dry and become covered with a yellowish crust. For this inoculation 10 to 15 minutes should be reserved.

13) Percutaneous inoculation is followed by a plain reaction, mainly local. In most cases, the general reaction is unnoticeable or absent. Local reaction symptoms begin to appear 8 to 14 hours after the inoculation and reach full development after 20 to 30 hours, in rare cases after 48 hours.

The reaction is evidenced at the place of inoculation by hyperemia, a small swelling, insignificant vesicles in the scratches, and, on occasion, infiltration in the skin. A general reaction in the form of fever or indisposition, and enlargement or tenderness in the regional lymph glands is seldom observed. If fever occurs, it is seldom above 37.5°C and usually does not last over a few days.

14) For subcutaneous inoculation, the dry vaccine contained in the ampules must be dissolved in the volume of physiological cooking salt solution called for on the vaccine label. Dilution of the vaccine is done according to the method described for intracutaneous inoculation. The diluted vaccine is injected, with observance of all the rules of asepsis, under the skin at the lower corner of the shoulder blade or under the skin of the shoulder, for adults and children over 14 in the amount of 1 cm^3, for children 10 to 14 in the amount of .5 cm^3, and for children 7 to 10 in the amount of .3 cm^3.

15) After subcutaneous inoculation, a local and a general reaction is observed:

a) The local reaction appears in almost all

cases, and is in the form of swelling, reddening, and pain at the place of inoculation. More rarely, the regional lymph glands show swelling. All of these symptoms begin developing 6 to 10 hours after the inoculation (more rarely after two or three days) and usually disappear after four to five days.

b) The general reaction is evidenced in indisposition, headaches, a rise in temperature up 37.5°C, more rarely up to 38-39°C, and in rare cases up to over 39°C. On occasion, nausea and vomiting occurs. The symptoms begin to appear during the first days, and disappear after one to two days.

16) When inoculations are being carried out, the vaccine in the bottle or in the ampule should be shaken each time before filling the syringe or the pipette. The syringe or pipette must contain only one dose at a time.

17) Medical control is kept of the inoculated persons in accordance with general rules.

18) Before the inoculations are begun, those to be vaccinated are registered in a special journal according to the following formula:

Last name First name Patronymic	Age	Sex	Address	Previous Inoc.	Date of vac.	Dose and vaccine series no.

Inoculation method	Character of the local & general reactions	Remarks

Without exception, all those subject to vaccination but not vaccinated are to be entered in another journal according to the same formula.

19) A certificate of vaccination must be issued for each vaccinated person.

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