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|                                | Instruction for Use | Effective Date | 2022-10-28          | Page    | 1 / 6 |



# Instructions for Use Of Disposable Sampling Swab

Model: 95000LV

**Revision records:**

| <b>Edition</b> | <b>Effective Date</b> | <b>Summary of revision</b> | <b>Approved by</b> | <b>Audited by</b> | <b>Written by</b> |
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| V1.0           | 2022-10-28            | Initial version            | Zhai Ying          | Cui Liu           | Chen miao         |
|                |                       |                            |                    |                   |                   |
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|                |                       |                            |                    |                   |                   |

# Instructions for Use

**[Product Name]**

Disposable Sampling Swab

**[Product Model]**

95000LV

**[Packaging Specification]**

| Model   | Single Package | Middle Package          | Transport Package |
|---------|----------------|-------------------------|-------------------|
| 95000LV | 1 pc/bag       | 10 pcs/bag, 50 bags/box | 500 pcs/box       |

**[Intended Use]**

The Disposable Sampling Swab is intended to collect biological samples from cervix of the human body for biological examination.

**[Intended Users]**

This device can be used both by professionals and lay users who are adults.

**[Description]**

The Disposable Sampling Swab consists of a plastic handle and sponge sampling head which is harmless to the human body and microorganisms and can maximize the collection and release of samples. The long handle is easy to hold and suitable for different groups of people. The Disposable Sampling Swab can form a sample collection system with the collection tube or transport tube.

**[Dimension]**

| Model   | Tip Width (mm) | Tip Length (mm) | Total Length (mm) |
|---------|----------------|-----------------|-------------------|
| 95000LV | 8mm            | 27mm            | 152mm             |

*Note: There is a certain deviation range for product dimension parameters.*

**[Contraindication]**

If any irritation or allergic reaction occurs, please stop use and ask a doctor.

**[Warnings]**

- 1) This is a single-use product, don't reuse it.

- 2) Keep away from flames or sparks.
- 3) Keep out of the reach of children.
- 4) Avoid soaking swabs with preservation solution before sampling.
- 5) Avoid repeated freezing-thawing.
- 6) If any damage of package, please do not use it.
- 7) If it is expired, please do not use it.
- 8) If you are allergic to sponge and plastic material, please do not use it.
- 9) The used products should be treated according to local medical waste regulations, and cannot be disposed of carelessly.

### **[Instructions for use]**

- 1) Peel apart the sterile package.
- 2) Use a semi-sit-down mode, hold the handle of swab and put the sampling swab into vagina, until the security block slice touches the vaginal orifice, the head of the swab is not spun out.
- 3) Rotate the swab head 5-6 times and put the swab into the vagina to sampling, keep the security block slice touching the vaginal orifice during the rotate process.
- 4) Remove the sampling swab from the vaginal orifice gently and put it into the collection tube, then keep the tube up and down 10-15 times and store it to complete the sampling.

### **[Product performance index]**

- 1) Basic dimensions: Basic dimensions of the product shall meet the requirements of the Dimension.
- 2) Appearance: The product should be clean, odorless, tasteless, and the swab should be soft to the touch. There should be no yellow spots, smudges, foreign objects, and the rod should be smooth.
- 3) Breaking Strength: The test span shall avoid the depression between the sampling head and the connecting rod, and the swab shall be able to withstand 4N static pressure perpendicular to the axial direction for 15s without permanent deformation or fracture.
- 4) Rotational friction: Rub the sampling head with a small piece of black paper or cloth on the table for at least 5 times by rotating friction 360 degrees, and detect that the materials of the sampling head will not fall off.
- 5) Connection Strength: When the moving speed of the tensile testing machine fixture is 200mm/min, the pulling force of the sampling head and one end of the connecting rod should be no less than 2N.
- 6) Maximum breaking force: The breaking force at the depression of the sampling head end shall not be less than 2N. The maximum breaking force vertically downward at the depression of the connecting rod at the fixed sampling head end (90° vertical downward

pressure) is 20N.

7) Sampling head firmness: According to the method in T/CSBME 013 (Chinese local standards), thread a 40cm long suture with a needle pass through the top of the sampling head and tie a knot (select the position at the top of the sampling rod that does not directly contact the material of the sampling head to prevent the needle from directly passing through the sampling rod to affect the detection), and hang a 50g weight for 10 seconds. The sampling head shall be firm and not fall off.

8) Water absorption of sampling head: Fill the purified water in a clean container, place it on a weighing balance with an accuracy of not less than 0.001g, and record the reading  $m_1$  of the balance. Immerse the sample head completely below the purified water level. After 15 seconds, the sample head is taken out vertically against the inner wall of the container (the sample head cannot be pressed hard). Record the indicated value of the balance  $m_2$ . The difference between  $m_1$  and  $m_2$  is the water absorption of the sample head. The water absorption of the sample head is  $\geq 0.02g$ .

9) Sterility: The product should be sterile after ethylene oxide sterilization.





#### [Period of Validity]














36 months

#### [Storage Conditions]

- 1) Be stored at room temperature.
- 2) It is recommended to be stored in a dry, ventilated, non-corrosive gas environment, away from ignition sources and flammable substances.
- 3) The product should be protected from heavy stress, direct sunlight, rain and snow in the transportation process.

#### [Graphs and symbols used for medical device labels]

| Symbol  | Description of symbol  | Symbol  | Description of symbol  |
|---|--|---|--|
|  | Indicates the medical device manufacturer.                           |  | Indicates the item is a medical device.                              |
|  | Indicates the need for the user to consult the instructions for use. |  | Indicates a medical device that is intended for one single use only. |

|   |   |   |   |
|---|---|---|---|
|    | Indicates the authorized representative in the European Community.  |    | Indicates the date when the medical device was manufactured.  |
|    | Indicates the date after which the medical device is not to be used.  |    | Indicates the manufacturer's batch code so that the batch or lot can be identified.   |
|    | Indicates the manufacturer's catalogue number so that the medical device can be identified.   |   | Indicates a medical device that has been sterilized using ethylene oxide.   |
|    | Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information. |    | Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. |
|  | Indicates a medical device that needs to be protected from moisture.  |  | Indicates a medical device that needs protection from light sources.  |
|  | Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.   |  | Indicates a carrier that contains unique device identifier information.   |
|  | This side up.   | /   | /   |



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