

# Instructions for Use

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**Product: Specimen Collection Swab**

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|------------------|---------------------------------|-----------------------|
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## Instructions for Use



### Product Name

Specimen Collection Swab

### Intended Use

Specimen Collection Swab is intended to be used as clinician-collected female and male throat swabs, buccal swabs and nasopharyngeal swabs (collected in a clinical setting).

This is a single use, disposable device(s), provided sterile, and it realizes intended use in combination with transport tube that not contain in the device and should be CE marked.



### Warning and precautions

1. Sterile only if peel-pouch in intact, This product is a disposable medical device. Product can't be reused or re-sterilized.
2. Before sampling, please check whether the package is in good condition. If it is damaged, please stop using immediately and contact the dealer or manufacturer for replacement
3. If allergic reaction occurs after use, please stop using immediately.
4. Please do not eat, smoke or drink 30 minutes before sampling to avoid affecting the sampling operation.
5. The disposal of device shall be carried out in accordance with national environmental protection laws and regulations.

### Instructions for use

#### Throat swab specimen collection

1. Wash hands with soap and water and don personal protective equipment.
2. Remove the swab from its packaging, holding by the end of the applicator and identify the breaking point.
3. Position head slightly back.
4. Depress the tongue so that the back of the throat can be seen.
5. Rub the swab up and down against the back of the throat, avoiding the tongue and cheeks
6. While holding the swab, remove the cap from the tube.
7. Discard the broken part of the applicator into an approved waste disposal container.
8. Screw the cap back onto the tube and apply patient identification label or write patient information on the tube label.

## 9. Wash hands with soap and water

**COLLECT THE SAMPLE**

Wash hands with soap and water and don personal protective equipment.



**1** Remove the swab from its packaging, holding by the end of the applicator and identify the breaking point.



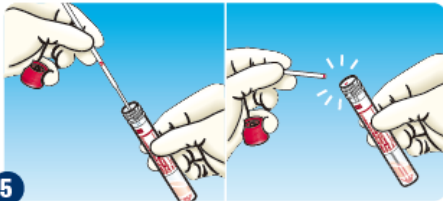
**2** Position head slightly back.



**3** Depress the tongue so that the back of the throat can be seen.



**4** Rub the swab up and down against the back of the throat, avoiding the tongue and cheeks.

**PACKAGE THE SAMPLE**

**5** While holding the swab, remove the cap from the tube.

- Insert the swab into the tube until the breakpoint is level with the tube opening.
- Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the swab shaft to complete the breakage.



**6** Discard the broken part of the applicator into an approved waste disposal container.




**7** Screw the cap back onto the tube and apply patient identification label or write patient information on the tube label.




Wash hands with soap and water.

**Nasopharyngeal swab specimen collection**


1. Wash hands with soap and water and don personal protective equipment.
2. Remove the swab from its packaging, holding by the end of the applicator and identify the breaking point.
3. Position head slightly back.
4. Gently insert the swab into the nostril. Keep the swab near the septum floor of the nose while gently pushing the swab into the post nasopharynx. As a visual reference, the swab should be inserted about half the distance from the opening of the patient's nostril and the ear.
5. When the swab is in place, rotate in a circular motion gently against the nasopharyngeal mucosa for 10 – 15 seconds then gently remove swab.
6. While holding the swab, remove the cap from the tube.
7. Discard the broken part of the applicator into an approved waste disposal container.
8. Screw the cap back onto the tube and apply patient identification label or write patient information on the tube label.
9. Wash hands with soap and water




Wash hands with soap and water and don personal protective equipment.



**1** Remove the swab from its packaging, holding by the end of the applicator and identify the breaking point.




**2** Position head slightly back.



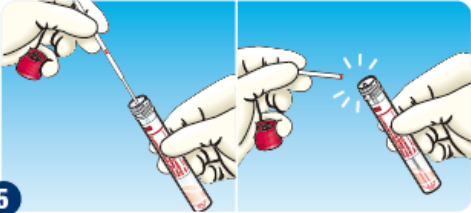
**3**

- Gently insert the swab into the nostril. Keep the swab near the septum floor of the nose while gently pushing the swab into the post nasopharynx.
- As a visual reference, the swab should be inserted about half the distance from the opening of the patient's nostril and the ear.




**4** When the swab is in place, rotate in a circular motion gently against the nasopharyngeal mucosa for 10 – 15 seconds then gently remove swab.

**PACKAGE THE SAMPLE**




**5**


- While holding the swab, remove the cap from the tube.
- Insert the swab into the tube until the breakpoint is level with the tube opening.
- Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the swab shaft to complete the breakage.



**6** **DISPOSAL**  
Discard the broken part of the applicator into an approved waste disposal container.



**7** Screw the cap back onto the tube and apply patient identification label or write patient information on the tube label.

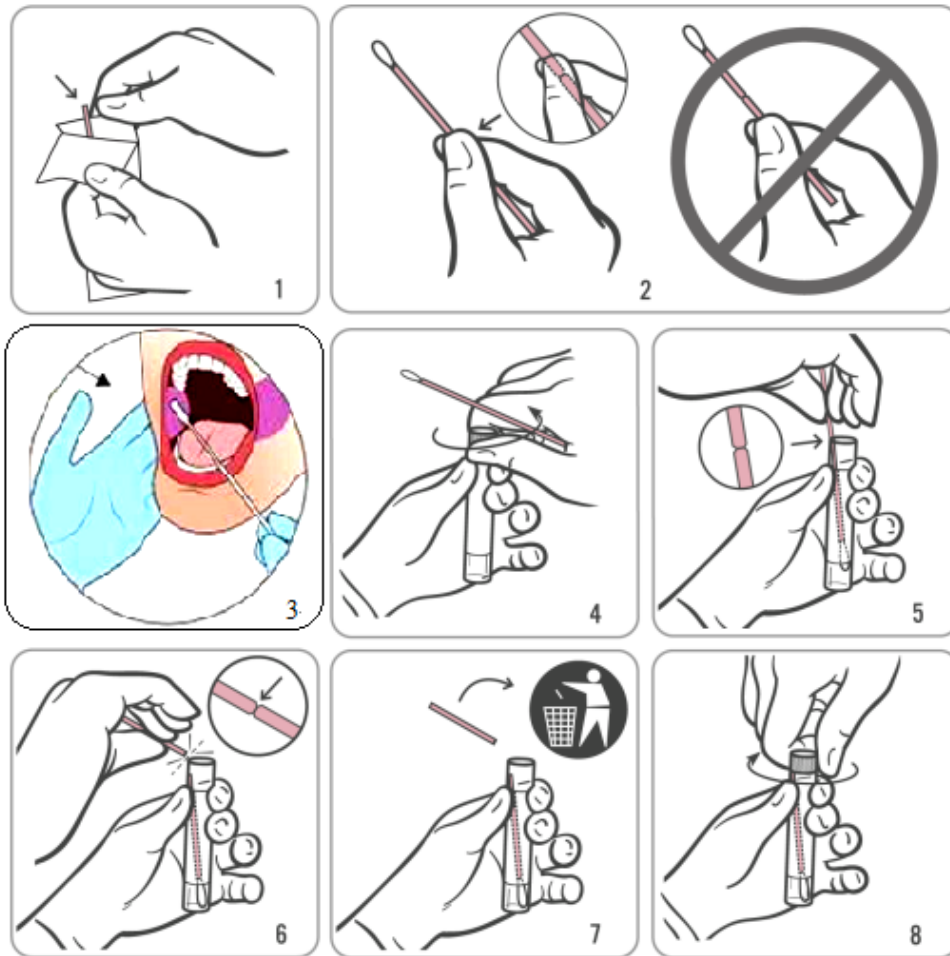


Wash hands with soap and water.

## Buccal specimen swab collection

1. Rinse the patient's mouth with water.
2. Partially peel open the swab package as shown in Diagram 1. Remove the swab.  
Do not touch the soft tip or lay the swab down.  
If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection swab.
3. Hold the swab as shown in Diagram 2, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
4. Insert oral swab into one side of the oral cavity in Diagram 3, rotate 10-20 circles from the inside to the outside, from the outside to the inside, and then move the swab up and down for 5-10 times, with moderate strength. It is better to cling to the oral cavity inner membrane, so as to ensure that all parts of the swab can dip into the exfoliated cells of the oral mucosa; according to the same method, collect on the other side of the oral cavity inner wall
5. While holding the swab in the same hand, unscrew the cap from the tube as shown in Diagram 4.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube as shown in Diagram 5. Use care to avoid splashing contents.
7. Carefully break the swab shaft at the score line against the side of the tube as shown in Diagram 6.
8. Immediately discard the top portion of the swab shaft as shown in Diagram 7.

9. Tightly screw the cap onto the tube as shown in Diagram 8



**Storage**

The product should be store in a room with a temperature of 2°C~ 40°C, relative humidity of less than 80%, no corrosive gases, and a well-ventilated room to avoid strong sunlight;


**Shelf life**
















3 years

**Sterilization method**

EO Sterilization

**Symbols meaning**

| Symbol     | Introductions | Symbol  | Introductions |
|------------|---------------|---|---------------|
| <b>LOT</b> | Batch Code    |  | Manufacturer  |

|   |   |   |                                  |
|---|---|---|----------------------------------|
|    | Caution   |    | Manufacture Date                 |
|    | Do not re-use                                       |    | Use-by date                      |
|    | Authorized representative in the European Community |    | Sterilized using EO              |
|    | CE mark and notified body code                      |    | Do not use if package is damaged |
|    | Keep away from sunlight                             |    | Fragile, handle with care        |
|  | Keep dry  |  | Do not re-sterilize              |
|  | This way up   |  | Consult instructions for use     |
|  | Temperature limit                                   |   |                                  |

## Manufacturer Information



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