

Package Insert & How-To-Use Guide

Oropharyngeal Flocked Nylon Swabs
Nasopharyngeal Flocked Nylon Swabs
Oropharyngeal Poly-Spun Swabs
Adult Mid-Turbinate Flocked Nylon Swabs
Pediatric Mid-Turbinate Flocked Nylon Swabs
Anterior Nares Swab

INTENDED USE

Shanghai Youding Oropharyngeal Flocked Swabs, Nasopharyngeal Flocked Swabs, Oropharyngeal Poly-Spun Swabs, Adult Mid-Turbinate Flocked Swabs, Pediatric Mid-Turbinate Flocked Swabs, and Anterior Nares Swab are sterilized via ethyl-oxide gas, individually wrapped in medical-grade paper peel-packaging and are designed for the collection of clinical samples. The swabs are suitable for brief contact with the human body. Shanghai Youding swabs are intended for use only as directed.

A very common procedure to diagnose infections is to use thin swabs to collect samples from patients. This can be done using Shanghai Youding swabs.

TECHNICAL NOTES

- Shanghai Youding swabs are packed into medical-grade paper peel-packs.
- Shanghai Youding swabs are sterilized via ethyl-oxide gas.

PRECAUTIONS

1. Carefully follow all instructions regarding use.
2. When using a swab during sampling, apply only light pressure as the plastic stick material is breakable.
3. The adhesive used to attach the fibers to the stick is only tested and intended for very brief contact during sample collection. Prolonged contact of the swab to the sampling area may cause some fibers to detach from the stick.
4. Do not submit swabs to a chemical or physical sterilizing or micro-biostatic process as its intended functioning could be compromised.
5. All swabs are single-use and cannot be reused or re-sterilized.

STORAGE

Store the Shanghai Youding swab devices at 36 – 86°F (2 - 30°C). Storing them at different temperatures will compromise the integrity of the swabs' specifications.

PRODUCT DETERIORATION

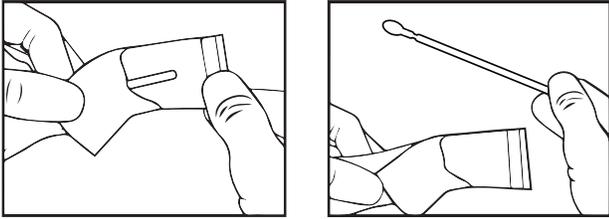
The content of the unopened and undamaged units is guaranteed to be sterile. Do not use Shanghai Youding swabs if:

1. The swab package is open or damaged
2. The expiration date has passed
3. There is evidence of damage or contamination to the product
4. There are other signs of deterioration

DIRECTIONS FOR USE, SPECIMEN COLLECTION

In addition to this document, descriptive diagrams are available on each unit.

1. Open the peel-packaging and remove the swab.



NOTE: Do not use excessive force, pressure, or bending when collecting swab samples from patients as this may result in unintended breakage of the swab shaft. Swab shafts often exhibit diameter changes to facilitate different sampling requirements. Swab shafts may also have a molded breakpoint designed for the intentional breakage of the swab into a transport tube. In all circumstances, when collecting swab samples from patients, do not use excessive force, pressure, or bending of the swab as this may result in accidental breakage of the swab shaft.

2. Collect the sample. Only the tip of the swab should come in contact with the suspected infection to reduce contamination risks during sampling.
3. Process the swab according to your internal laboratory procedures. Alternatively, put the swab in a transport tube.
4. Send the sample to the laboratory for immediate testing.

Specimens collected for clinical investigations should be collected and handled while following published manuals and guidelines.

Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations. Shipping of specimens within medical institutions should comply with the internal guidelines of the institution.

LIMITATIONS

1. In the laboratory, wear protective gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe biosafety recommendations when handling or analyzing patient samples.
2. Condition, timing, and volume of specimens collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
3. Shanghai Youding swabs must be used by skilled personnel only.

WARNINGS

1. This product is for single use only. Reuse may cause a risk of infection and could lead to inaccurate results.
2. Do not re-sterilize unused swabs.
3. Do not re-pack.
4. Not suitable for any other application than intended use.
5. Please validate the use of this product in association with a rapid diagnostic kit or other diagnostic instrumentation before implementation.
6. Do not use if the swab is visibly damaged (i.e., if the swab tip or swab shaft is bent or broken).
7. Do not use excessive force, pressure, or bending when collecting swab samples from patients as this may result in accidental breakage of the swab shaft.
8. Follow directions for use carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
9. To be handled by skilled personnel only.
10. Assume that all specimens contain infectious micro-organisms, and handle with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

WASTE DISPOSAL

- Unused swabs may be considered as non-hazardous waste and disposed of accordingly.
- Dispose of used swabs, as well as any other contaminated disposable materials, following procedures for infectious or potentially infectious products.
- Each laboratory is responsible for handling waste and effluents produced according to their nature and degree of hazardousness. Each laboratory is additionally responsible for the treatment and disposal of the waste (or have them treated and disposed of) per applicable regulations.