

Instructions for Use (IFU) Microbrush Test Swabs

by Young Innovations

INTENDED USE:

Microbrush Test Swabs are sterile and ready-for-use systems intended for clinical samples drawing. The swab is suitable for short contact with the human body. Product should be used as directed.

SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of infections involves the collection of swab samples. This can be accomplished using Microbrush Test Swabs.

Microbrush Test Swabs are available with different sizes and shapes of both shaft and tip for different body collection sites.

The Microbrush Test Swabs are packed into a medical grade paper or plastic pouch and are EO sterilized. The sterilization type is indicated on the product labels (pouch, carton and/or box labels).

TECHNICAL NOTES

A slight yellowing of the tip is a well-known phenomenon. This could be due to many factors: to the type of raw material, to the product sterilization treatment, to the product natural aging. Therefore product yellowing is not necessarily indicative of product deterioration.

PRECAUTIONS

1. Carefully follow the instructions for use.
2. When using the device, pressure applied during sampling shall be light since the stick material is breakable.
3. The fiber adhesion to the stick is tested for instantaneous sampling; a longer contact between the swab and the sampling area might cause the fiber to come out.
4. If the swab is submitted to a chemical or physical sterilizing or micro-biostatic process, its intended functioning could be compromised.
5. Product can not be reused or re-sterilized.

STORAGE

Store Microbrush Test Swabs in a room temperature, dry location that is away from direct sunlight. If product is stored in different conditions, it will not maintain stated specifications.

PRODUCT DETERIORATION

The content of the unopened and undamaged units is guaranteed to be sterile.

Microbrush Test Swabs should not be used if (1) there is evidence of damage or contamination to the product, (2) the expiration date has passed, (3) the swab package is open or damaged, or (4) there are other signs of deterioration.

DIRECTIONS FOR USE, SPECIMEN COLLECTION

In case the swab is packaged with other items in a kit, follow all other provided instructions for use.

NOTE: Sterile gloves, protective clothing and eyewear should be worn when collecting and handling microbiology specimens.

1. Open the pouch and take out the swab.
Do not touch the sample end of the swab.
2. Collect the sample. During sampling, the swab end (tip) shall only come in contact with the suspected infection, so as to reduce contamination risks.
3. Process the swab according to internal laboratory procedure.
Alternatively put the swab in the transport test tube. *See Figure 1*
4. If required, break the swab using a rapid, swift motion. If the swab does not break cleanly, a slight twisting motion may be required to complete separation.
5. Send the sample to the laboratory for immediate testing.

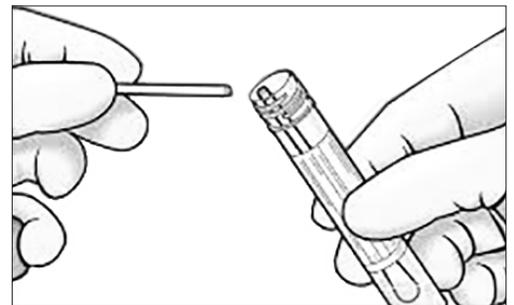


Figure 1

Specimens collected for clinical investigations should be collected and handled 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 internal guidelines of the institution.

NOTE: 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. Swab shafts often exhibit diameter changes to facilitate different sampling requirements. Swab shafts may also have a molded breakpoint point designed for intentional breakage of the swab into a transport tube. Use a swift, deliberate motion when intentionally breaking the swab at the break off portion for insertion into the transport tube in all circumstances when collecting 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.

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 specimen collected for clinical investigation are significant variables in obtaining reliable results. Follow recommended guidelines for specimen collection.
3. Microbrush Test 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/or 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. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
6. Do not use if the swab is visibly damaged (i.e., if the swab tip or swab shaft is 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. Directions for use must be followed carefully. The manufacturer cannot be held responsible for any unauthorized or unqualified use of the product.
9. To be handled by trained personnel only.
10. It must be assumed that all specimens contain infectious micro-organisms; therefore all specimens must be handled 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. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with applicable regulations.

Symbol	Definition
	Product reference number
	Batch or Lot code
	Expiration Date
	See instructions for use
	eIFU See instructions for use
	Sterilized using ethylene oxide
	Single Use Only
	Do not use if pouch is damaged
	Avoid direct sunlight
	Keep dry

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Made in USA
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