



FLOQSwabs[®] hDNA Free

Non-sterile hDNAfree FLOQSwabs[®] device

Package insert and How-to-use guide

NON STERILE hDNAfree FLOQSwabs[®] Package insert & User Guide

INTENDED USE

The non-sterile hDNAfree FLOQSwabs[®] device is a ready-for-use system intended for the collection of biological specimens from the human body.

PRODUCT DESCRIPTION

The non sterile hDNAfree FLOQSwabs[®] device is a swab supplied into a labeled tube in a transparent bag. The swab shaft is inserted into the tube cap which acts as grip. The tube cap include an Active Drying System. The Active Drying System consists of a desiccant intended to absorb the moisture of the sample collected aiding its preservation.

The swab has a standard tip and a breakpoint that allows easily breaking the swab tip inside a test tube after taking the sample. The device is subjected to a treatment with ethylene oxide and it is free of amplifiable human DNA, DNase and RNase.

PRODUCT STORAGE

The product is ready to use and does not require additional preparation. It must be stored in its original package at a temperature between 2 and 30°C until the

time of use. Do not overheat. Do not incubate or freeze prior to use. If incorrectly stored, its effectiveness will be compromised. Do not use after the expiry date clearly printed on the tube and on box label.

LIMITATIONS

1. The product is not sterile and it is not suitable for ocular collection or for sampling from wounds and in all the collection procedures that requires asepsis.
2. The specimen collected with non-sterile swabs for microbiological diagnostic investigations should not be analyzed using culture methods.
3. Not suitable for collecting specimens to be analyzed using microscopic identification (e.g. Gram staining).
4.  This product is intended for single use. Reuse may lead to a risk of cross-contamination and/or inaccurate results.
5. The collection and transport conditions, the times and volume of the samples collected for clinical investigation are significant variables for obtaining reliable results.
6. This device may only be used by adequately trained and qualified personnel.

WARNINGS AND PRECAUTIONS FOR USE

1. Carefully follow the instructions for use.
2. The product is not suitable for applications different from the intended use.
3. The appropriate environment for use of a non sterile device should be defined by the healthcare professional based on the diagnostic investigation and the collections site.
4. Do not sterilize the device before use.
5. Do not bend or model the swab before collecting the sample or force or excessively press when taking the sample from the patient as this may cause accidental breakage of the shaft or its detachment from the cap.
6. Do not detach the shaft from the grip (tube cap).
7. The product is ready to use: it does not have to be pre-treated or moistened before taking the sample.
8. The amount of sample collected varies considerably from one donor to the next and depends on the collection procedure.
9. In order to prevent sample contamination, wear disposable gloves, a mask and a cap, and other protection devices in line with the general precautions.
10. In the laboratory, the use of this product in combination with preservation culture mediums, rapid diagnostic kits or diagnostic instruments must be validated by the user in advance.
11. All samples taken should be considered potentially infected, therefore, maximum caution is recommended when handling the sample.
12. The use of this product in combination with rapid diagnostic kits, extraction and amplification kits or other instruments must always be validated by the user.
13. Do not use if the swab or the transparent bag is visibly damaged (e.g. if the swab tip or shaft is broken).
14. Unused products, waste and the samples must be disposed of in compliance with the local regulations.

PRODUCT DETERIORATION

Do not use non sterile hDNAfree FLOQSwabs[®] device if 1. the product shows signs of damage or contamination; 2. the product has passed its expiry date;

3. the swab package is open and/or the protective seal on the tube is not intact.

INSTRUCTIONS FOR USE

Sample collection

Correctly collecting the sample from the patient is crucial for the outcome of a clinical investigations. For specific instructions on the sample collection procedures, refer to the procedure described below or to the internal collection procedures.

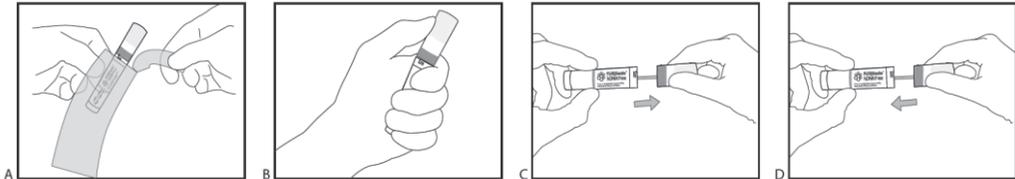
During sample collection and handling, wear protective clothing, gloves and goggles.

Hold the swab by the grip when taking the sample.

NOTE: The sample must be collected immediately after opening the transparent bag.

NOTE: Do not force or excessively press or bend the swab when taking the sample from the patient, as this may result in accidental breakage of the shaft. The swab shaft has a moulded breakpoint in proximity of the tip, which allows intentionally breaking the swab inside a test tube.

1. Put on gloves, open the bag and remove the plastic tube (Figure 1A).
2. To facilitate the opening of the tube cap, hold the swab by the plastic tube with one hand and with your thumb press the top of the white cap (Figure 1B).
3. Holding the swab by the grip (white cap), remove the swab from the plastic tube and place the tube on a clean surface (Figure 1C).
4. Collect the sample. During sampling, the swab end (tip) shall only come in contact with the collection site, so as to reduce contamination risks.
5. Once you have taken the sample, put the swab back into the plastic tube and securely close it (Figure 1D).
6. Identify the collected sample. Send the sample to the laboratory for testing as soon as possible.



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.

Table of Symbols

Symbol	Meaning
	Manufacturer
	Do not reuse
	Catalogue number
	Temperature limits
	Use before
	Consult the instructions for use
	Batch code (lot)
	Contents sufficient for <n> tests
	Do not use if the packaging is damaged
	Non-sterile



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