EN

SELF-SAMPLING KIT FOR VAGINAL SAMPLE

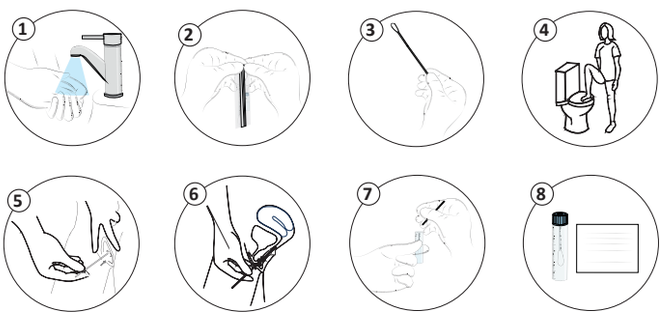
Read the instructions for use carefully before using the product. Single-use product. Sterile.
The product is intended to be used by lay users.

INTENDED PURPOSE:
Kits for the self-collection and transport of vaginal samples for subsequent microbiological analysis through in vitro examination.

PRESENTATION:
The kits are in vitro diagnostic medical devices and consist of flocked swabs accompanied by an empty tube or a tube containing transport medium. The swabs are medical devices and the tubes with and without transport medium are in vitro diagnostic medical devices. The self-sampling kits for vaginal samples are individually packaged. This kit may be sterile or non-sterile.
The sterilization method is specified on the individual packaging.
The kit does not include the material required for the isolation and culture of microorganisms.

HOW TO USE:
1. Make sure you have all the components (swab and instructions for use).
2. Before self-sampling, read the precautions carefully and then follow the instructions below to collect the vaginal sample with the swab.
3. Store the sample in its tube. Keep the sample refrigerated if it cannot be delivered within the first 24 hours.
4. Return the sample according to the indications.

INSTRUCTIONS FOR COLLECTING THE VAGINAL SAMPLE:
1. Clean your hands and open the wrapper.
2. Carefully remove the swab without touching the absorbent tip.
3. Hold the swab about 6 cm from your head.
4. Place yourself in a comfortable position, preferably standing with a leg raised, as shown in the figure.
5. Insert the swab into the vagina, about 6 centimeters. Rotate the swab at least three times, ensuring the head touches the internal walls of the vagina.
6. Slowly remove the swab, avoiding contact with the external walls of the vagina or the head of the swab with your hands.
7. Place the swab in the tube, break it at the rupture zone, and cap the tube with the swab inside. Ensure the tube is properly sealed.
8. Add the date and your personal information (full name) to the product identification label.



SAFE DISPOSAL OF THE PRODUCT, ITS ACCESSORIES, AND CONSUMABLES:
Dispose of excess material in accordance with current legislation.

STORAGE AND STABILITY DURING USE:
Before use, the product must be stored in a dry place away from direct sunlight.
In the case of kits with transport medium tubes, the product must be stored at a temperature between 2°C and 30°C.
Do not use the product after the expiry date indicated on the label or packaging.
Compliance with these storage conditions guarantees the stability and correct functioning of the product throughout its shelf life.

WARNINGS AND PRECAUTIONS:

Use of the kit poses no difficulty for the intended user, provided that these instructions for correct sampling and storage until delivery to healthcare personnel are followed. You may also consult the explanatory video via the QR code on the labelling of the product packaging and in this document. If you have any questions about the procedure, consult the healthcare personnel. Inadequate sampling could give rise to false negative results.

- Do not use if some component is missing or if the printed information on the product is not clearly visible.

- Unused swabs can be considered non-hazardous products and can be disposed of according to this criterion.

- Do not perform vaginal self-sampling while you are menstruating. At least 4 days must have passed since your last bleeding before performing a self-sampling.

- Do not perform self-sampling if you are pregnant or within three months of giving birth.

- Do not use vaginal creams or douches for three days prior to self-examination.

- Do not have sexual relations or gynecological examinations two days before self-sampling. Not suitable for any other than its intended use.

- Do not use if there is evidence of damage to the packaging.

- If the single-unit container is damaged, do not use the swab, since sterility is not guaranteed. Do not use if there is evidence of dirty or if the swab is broken, or present sharp edges or is missing the head. For single use only, reutilisation of this product can cause infections.

- Handle the swab with care. Although unlikely, applying too much pressure during use could break the swab. Discard immediately, if broken.

- Do not eat, drink, or smoke during sample collection. Once sample collection is complete, dispose of the remaining material according to current legislation.

*For additional information regarding sample processing, please refer to the electronic version of the instructions for use, "Flocked Swab Sample Collection Kit," REF 905074 TEC 1707, available at www.deltalabgroup.com/eifus.

REFERENCE	DESCRIPTION	CE MARKING
200391.SV	FLOCK ST 100 FLOW SELFSWAB VAGINAL	CE IVD
200392.SV	FLOCK ST 100 TUBE SELFSWAB VAGINAL	
304238KF.SV	VICUM 2ML FLK ST 80 FLOW SELFSWAB VAGINAL	
304221KF.SV	AMIES 1ML FLK ST 80 FLOW SELFSWAB VAGINAL	IVD CE 0318

Consult video with detailed instructions

List of symbols:

REF	Catalogue number	LOT	Batch number		Please refer to the precautions in the instructions for use		Expiry date	STERILE R	Sterilised by irradiation
	Manufacture date		Single sterile barrier system	www.deltalabgroup.com/videos-ifu	Consult instructions for use video on the website www.deltalabgroup.com/videos-ifu		Do not reuse	STERILE EO	Sterile by ethylene oxide
MD	Medical device		Do not use if packaging is damaged	www.deltalabgroup.com/eifus	*Consult the instructions for use on the website www.deltalabgroup.com/eifus*		Keep dry	CE 0318	CE Marking
	Manufacturer					Patient identification		Date	Heath care centre or doctor
UDI	Unique device identifier	QTY	Quantity	IVD	In vitro diagnostic medical device				

Report any serious incident* related with the product to both Deltalab, S.L. and to the competent authority in the country of the user. *A "serious incident" is an incident involving death or serious health problems for the patient or user, or a serious public health threat.

Sterile kit: IVD CE 0318 Non-sterile kit: CE IVD

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