

SELF-SAMPLING KIT FOR NASAL SAMPLES

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 nasal 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 a tube containing transport medium. The swabs are medical devices and the tubes with transport medium are in vitro diagnostic medical devices. The self-sampling kits for nasal samples are individually packaged and sterilized.

The sterilization method is specified on the individual packaging.

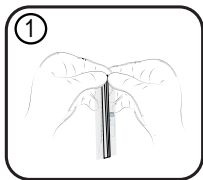
The kit does not include the material required for the isolation and culture of microorganisms.

How to use:

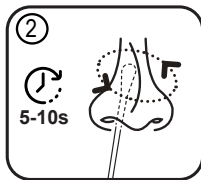
1. Make sure you have all the components (swab and instructions for use).
2. Before self-sampling, read the precautions carefully and then follow the instructions below to collect the nasal sample with the swab.
3. Store the sample in the tube.
4. Return the sample according to the indications.

Instructions for collecting the nasal sample:

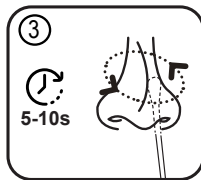
Self-sampling by the patient is to be carried out as follows:



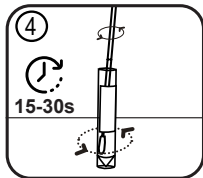
Open the kit with both hands and remove the tube and swab.



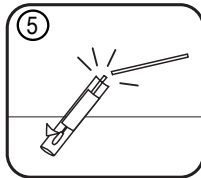
Insert the swab about 2 cm into one of the nostrils and rotate to rub it against the inner walls of the nose.



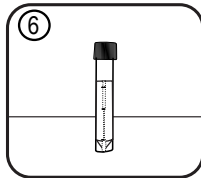
Repeat the same process in the other nostril.



Insert the swab into the tube, avoiding contact with the exterior, and rotating it against the walls.



Break the swab and leave it inside the tube.



Write the name and date of collection of the sample on the tube label and deliver the closed tube to a health professional.

General precautions:

1. Not suitable for any other than its intended use.
2. Use of the swab poses no difficulty for the intended users.
3. The swabs with transport medium include instructions for use with figures in the primary packaging, along with a QR code offering an explanatory video of how the user should perform correct sampling and storage until delivery to the health personnel.

Warnings:

1. If the single-unit swab container or tube is damaged, do not use, since sterility is not guaranteed.
2. Do not use if some component is missing or if the printed information on the product is not clearly visible.
3. Discard the product if the swab is dirty, broken and/or splintered and/or with a missing headpiece.
4. Do not use beyond the expiry date stated on the packaging.
5. Do not use if the transport medium shows any alterations.
6. Do not eat, drink, or smoke during sample collection. Wash or rinse with plenty of water if the liquid comes into contact with the skin, eyes or mouth. Do not ingest. Do not inhale.
7. Single-use product. Reutilisation of this product can cause infections.
8. Handle with care. Although unlikely, applying too much pressure during use could break the swab. Discard immediately if broken.
9. The swab with transport medium should be stored in a dry place protected from sunlight and at a temperature of 2-30 °C.
10. Once sampling has been completed, dispose of the remaining material according to current legislation.

If you have any questions about the procedure, consult the healthcare personnel. Inadequate sampling could give rise to false negative results.

*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
304244K.SN	VIRUS 3ML FLK ST 80 SELF5WAB NASAL



Consult video with detailed instructions

List of symbols:

REF Catalogue number	LOT Batch number	 Consult the instructions for use on the website www.deltalabgroup.com/eifus	QTY Quantity	STERILE R Sterilised by irradiation
IVD In vitro diagnostic medical device	 Keep dry	 Consult instructions for use video on the website www.deltalabgroup.com/videos-ifu	 Do not use if packaging is damaged	 Do not reuse
 Single sterile barrier system	 Manufacturer	 Expiry date	 CE 0318 CE Marking	 Storage temperature
UDI Unique device identifier	 Manufacture date	 Keep away from sunlight	 Patient identification	 Health care centre or doctor

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.