

## SELF-SAMPLING KIT FOR RECTAL 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 rectal 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 rectal 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 rectal 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 PHARYNGEAL SAMPLE:

1. Clean your hands and open the wrapper.
2. Carefully remove the swab without touching the absorbent tip.
3. Hold the swab about 3-4cm away from the absorbent tip.
4. Position yourself comfortably and insert the swab into the rectum, about 2 to 3 centimeters.
5. Rotate the swab between 5 and 10 times.
6. Rotate also when removing it.
7. Place the swab in the tube, break it at the rupture zone.
8. Cap the tube with the swab inside. Ensure the tube is properly sealed.
9. Add the date and your personal information (full name) to the product identification label.



### 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. The swabs do not require any special maintenance.

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

Wash or flush with plenty of water if liquid comes in contact with skin, eyes or mouth. Do not swallow. Do not inhale. It is advisable to store the swabs with transport medium in a dry place, protected from sunlight and at a temperature between 2-30°C.

Not suitable for any other than its intended use.

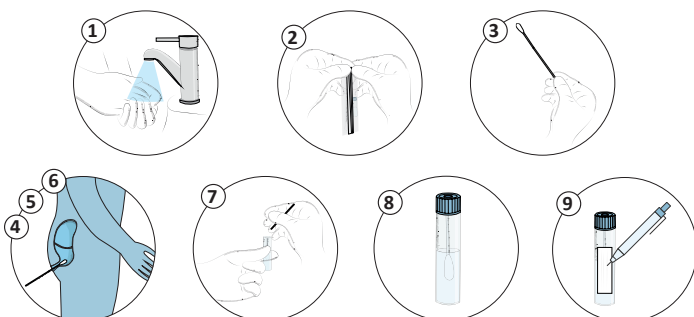
Do not use if there is evidence of damage to the packaging. If the single-unit container is damaged, do not use the swab, since sterility is not guaranteed. Do not use if there is evidence of dirty or if the swab is broken, or present sharp edges or is missing the head. For single use only, reutilisation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

Do not use beyond the expiry date stated on the packaging.

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 further information regarding sample processing, please refer to the electronic version of the instructions for use for the "Flocked Swab Sample Collection Kit", REF 905074 TEC 1707, available at [www.deltalabgroup.com/eifus](http://www.deltalabgroup.com/eifus).



| REFERENCE   | DESCRIPTION                               | CE MARKING  |
|-------------|-------------------------------------------|-------------|
| 304221KF.SR | AMIES 1ML FLK ST 80 FLOW SELF-SWAB RECTAL | IVD CE 0318 |
| 304238KF.SR | VICUM 2ML FLK ST 80 FLOW SELF-SWAB RECTAL | CE IVD      |



Consult video with detailed instructions

### Glossary of symbols:

|                                                                                     |                                    |                                                                                     |                              |                                                                                     |                                                                                                                                          |                                                                                       |                                   |                                                                                       |                           |
|-------------------------------------------------------------------------------------|------------------------------------|-------------------------------------------------------------------------------------|------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------|---------------------------------------------------------------------------------------|---------------------------|
| <b>REF</b>                                                                          | Catalogue number                   | <b>LOT</b>                                                                          | Batch number                 |  | Consult instructions for use video on the website <a href="http://www.deltalabgroup.com/videos-ifu">www.deltalabgroup.com/videos-ifu</a> |  | Expiry date                       | <b>STERILE R</b>                                                                      | Sterilised by irradiation |
| <b>IVD</b>                                                                          | In vitro diagnostic medical device | <b>CE 0318</b>                                                                      | CE Marking                   |  | Consult the instructions for use on the website <a href="http://www.deltalabgroup.com/eifus">www.deltalabgroup.com/eifus</a>             |  | Do not reuse                      | <b>31</b>                                                                             | Date                      |
|  | Keep away from sunlight            |  | Manufacturer                 |  | Do not use if packaging is damaged                                                                                                       |  | Storage temperature<br>2°C - 30°C |  | Precautions               |
| <b>UDI</b>                                                                          | Unique device identifier           |  | Manufacture date             |  | Single sterile barrier system                                                                                                            |  | Keep dry                          | <b>QTY</b>                                                                            | Quantity                  |
|  | 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.



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