



## INSTRUCTIONS FOR USE

### CHORUS ELASTASE COPROCOLLECT

#### For *In Vitro* Diagnostic Use Only

#### 1. INTENDED PURPOSE

Single-use device for manual collection of the amount of faeces required to perform the CHORUS CLIA FECAL ELASTASE (REF 82304) and CHORUS FECAL ELASTASE (REF 86114) kits.

The device should only be used by professional laboratory personnel.

#### 2. INTRODUCTION

The device for stools collection allows to collect the amount necessary to perform the CHORUS CLIA FECAL ELASTASE and the CHORUS FECAL ELASTASE tests directly from the primary container without having to weigh the sample.

#### 3. PRINCIPLE OF THE METHOD

The device consists of a tube containing the extraction solution and a shaped dipstick with seven radial grooves for sample collection. The upper end of the device consists of two removable parts with opposite rotations.

The screw cap (white), connected to the stick, is removed by turning it in anti-clockwise direction; the funnel (green), used to retain the coarsest stool impurities, can be removed with the white screw cap by turning it clockwise.

After performing this procedure, the sample can be transferred into the collection tube.

#### 4. WARNINGS AND PRECAUTIONS

##### FOR *IN VITRO* DIAGNOSTIC USE ONLY

Wait until stools samples reach room temperature (18-30°C) before collecting the samples.

The product, once used or expired or in case of deterioration, must be treated as infectious residuals and eliminated according to law.

#### Health and Safety Information

- All material of human origin must be handled as potentially infectious. All the samples must be handled according to the safety precautions normally adopted in laboratory practice.
- Wear disposable gloves and eye protection while handling specimens.
- Wash hands thoroughly after use.
- Spillage of potentially infectious materials should be removed immediately with adsorbent paper tissue and the contaminated area swabbed with, for example, 1% sodium hypochlorite before work is continued. Sodium hypochlorite should not be used on acid-containing spills unless the spill area is first wiped dry. Materials used to

clean spills, including gloves, should be disposed of as potentially biohazardous waste. Do not autoclave materials containing sodium hypochlorite.

#### Analytical Precautions

- Place unused devices in the primary package.
- Make sure that the product packaging is intact.
- Verify that the device is correctly closed.
- Do not use broken or damaged devices.
- Do not use the device in case of liquid leakage.
- Do not use the device after the expiration date.
- Adopt all the precautions to avoid contamination of the product during its use.

#### 5. KIT COMPOSITION

The package is sufficient for 18 determinations.

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Vortex
- Centrifugal machine
- Micropipettes for the accurate collection of 50-200 µl volumes
- Disposable gloves
- Sodium Hypochlorite solution (5%)
- Containers for collection of potentially infectious materials

#### 6. STORAGE AND STABILITY OF REAGENTS

Reagents must be stored at 2/8°C.

The expiry date is printed on the external label of the package.

#### 7. SPECIMEN COLLECTION AND STORAGE

- The collection device containing the stools sample must be stored at 2-8°C or at room temperature (18-30°C) and processed within 96 hours after collection (see chapter 8 Procedure).
- The faecal extract can be stored at 2-8°C for a maximum of 48 hours or can be frozen at temperature ≤ -20°C according to the Instructions for Use of the CHORUS CLIA FECAL ELASTASE and the CHORUS FECAL ELASTASE tests.
- In case of temporary unavailability of the device, keep the stools in the sterile primary container for no more than 96 hours at 2-8°C or at room temperature (18-30°C). For longer periods, freeze at temperature ≤ -20°C.

#### 8. ASSAY PROCEDURE

##### Procedure for stools collection

Sampling procedure for faeces of normal consistency:

- To collect a stools sample pull out the shaped stick by turning the white screw-cap in anti-clockwise direction.
- Dip the shaped stick in the stools sample.
- Repeatedly rotate the stick in the stools sample until all the grooves are filled with faecal material.
- Before inserting the stick into the device, remove the faecal material in excess by rotating the stick on the internal wall of the primary container.
- Fully insert the shaped stick, with faecal material, into the tube containing the extraction solution and turn the cap clockwise until it is completely closed, keeping blocked the

funnel (green) to avoid its opening clockwise until it is completely closed, holding the funnel (green) in place so as to prevent it from opening.

Sampling procedure for faeces of hard consistency (the shaped stick can hardly be dipped into the sample):

1. Pipette 50-100 µl of saline solution inside the stools container.
2. Keep the container with the stools and the saline solution at room temperature for 60 minutes at least.
3. Proceed following the instructions for "Sampling procedure for faeces of normal consistency" from point 2.

Sampling procedure for liquid faeces or anyhow having a consistency that does not allow the use of the shaped stick:

1. A laboratory pipette is necessary.
2. By using the pipette, aspirate 56 µl of liquid faeces.
3. Pull out the shaped stick and the funnel (green) by turning the funnel clockwise.
4. Pipette the liquid faeces sample directly into the collection device.
5. Fully insert the shaped stick back into the tube and turn the funnel (green) in anti-clockwise direction, until it is completely closed.

Sampling procedure for frozen faeces:

1. In case the sample is frozen, let the sample reach room temperature before collecting it with the device.
2. Proceed following the instructions for "Sampling procedure for faeces of normal consistency" from point 2

### Laboratory procedure

Follow the procedure described below for all the samples, whichever collection procedure has been used.

1. Shake the device by vortex for 60 seconds in order to properly homogenate the content.
2. After the stirring, remove the screw-cap (white) and the funnel (green) by turning the funnel clockwise.
3. Close the tube with the extra screw-cap (present in the package) and centrifugate it for at least 10 minutes at 1500 g.
4. After the centrifuge, transfer the supernatant into a clean tube making sure to not touch the pellet on the bottom of the tube.
5. The faecal extract is now ready to be tested following the Instructions for Use of the CHORUS CLIA FECAL ELASTASE (REF 82304) and CHORUS FECAL ELASTASE (REF 86114) kits.

If you have any problem please contact Customer care:

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[customercare@diesse.it](mailto:customercare@diesse.it)

### 9. INCIDENT REPORTING

If any serious incident in relation to this device has occurred in the European Union market territory, please report without delay to the manufacturer and competent authority of your Member State.