

Universal Sample Turbilatex[®] Vial

Sample collection and dilution vial for stool specimens

Instructions for use

IU-MST-0019URen0526 v.00

The test should be used by professional personnel

CE IVD

This instruction for use applies to the following references:

MST-0019UR

Product	Reference	UDI-DI
Universal Sample Turbilatex® Vial	MST-0019UR	08435440260479

Table 1 Reference and UDI-DI for *Universal Sample Turbilatex® Vial* reagents kit.

NOTE: The user should notify the manufacturer and the competent authority of the Member State in which he is established as the user and/or patient of any serious incident related to the product.

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1. Intended Purpose

Universal Turbilatex® Sample Vial is an *in vitro* diagnostic single-use sample collection/dilution vial. It is intended for the collection, dilution and preparation of human stool samples prior to analysis with compatible *in vitro* diagnostic assays on a clinical chemistry analyzer. It is not an automated assay.

It is intended for professional use only. The product has no analytical measuring function and is not intended, by itself, for the detection, quantification or interpretation of any analyte.

2. Storage and Stability

The product must be stored at temperature (2-30°C). Do not freeze.

Sample diluents are stable up to the expiration date printed on the label, always considering that vials must be properly closed to avoid any contamination, must be kept away from the sunlight and conserved at 2-30°C.

3. Precautions for users

- **Universal Turbilatex® Sample Vial** is for *in vitro* diagnostic use only.
- The product is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in Turbidimetric technique, autoanalyzer use and *in vitro* diagnostic procedures.
- This product is not intended for self-testing or near-patient testing (point-of-care use).
- The analyser should be ready before performing any assay.
- Read the instructions for use carefully before use the kit. Do not perform the test without fully understanding the information on procedures, safety precautions and limitations described in this instruction for use.
- Do not use after expiration date.
- Do not use the reagents if pack is damaged or opened.
- Do not freeze to maintain the integrity and performance of the test.
- Sample diluent does not contain materials of human origin.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.
- All the specimens should be considered potentially hazardous as well as all the materials that have been exposed to the samples and they must be handled according to the local or national safety regulations. Must be handled in the same manner as an infectious agent. Use proper infection control practices. These practices should include, but are not limited to, personal protective equipment (PPE), such as laboratory coat, surgical or appropriate mask, or face shield, disposable gloves, and eye protection. Take necessary precautions during the collection, transport, storage, handling, and disposal of the samples.

- In accordance with Regulation (EC) No 1907/2006 (REACH), **Universal Turbilatex® Sample Vial** do not require Material Safety Data Sheet on account of their classification as non-hazardous to health and the environment, because these kits do not contain substances and/or mixtures which meet the hazard classification criteria available in Regulation (EC) No 1272/2008 (CLP) or which are in concentrations higher than the value established in the mentioned regulation for their declaration. A statement declaring no requirement of Material Safety Data Sheet could be requested to Certest Biotec.
- The solutions should be discarded in a proper container after testing following local regulations.
- For the correct traceability of the sample, each **Universal Turbilatex® Sample Vial** used must be perfectly recognisable including patient identification.

4. Reagents

1. Materials provided

MST-0019UR **Universal Turbilatex® Sample Vial** contains buffer and sodium azide <0.1% as preservative, (100x2.00 mL).

2. Materials and instruments that could be required, but no provided

- Specimen collection container
- Shaker
- Microcentrifuge (10000g)
- Disposable gloves and laboratory equipment

3. Compatible reagents

- **FOB Turbilatex® Combo**
- **Transferrin Turbilatex® Combo**
- **Calprotectin Turbilatex® Combo**
- **Pancreatic Elastase Turbilatex® Combo**

5. Specimen Collection and Preparation

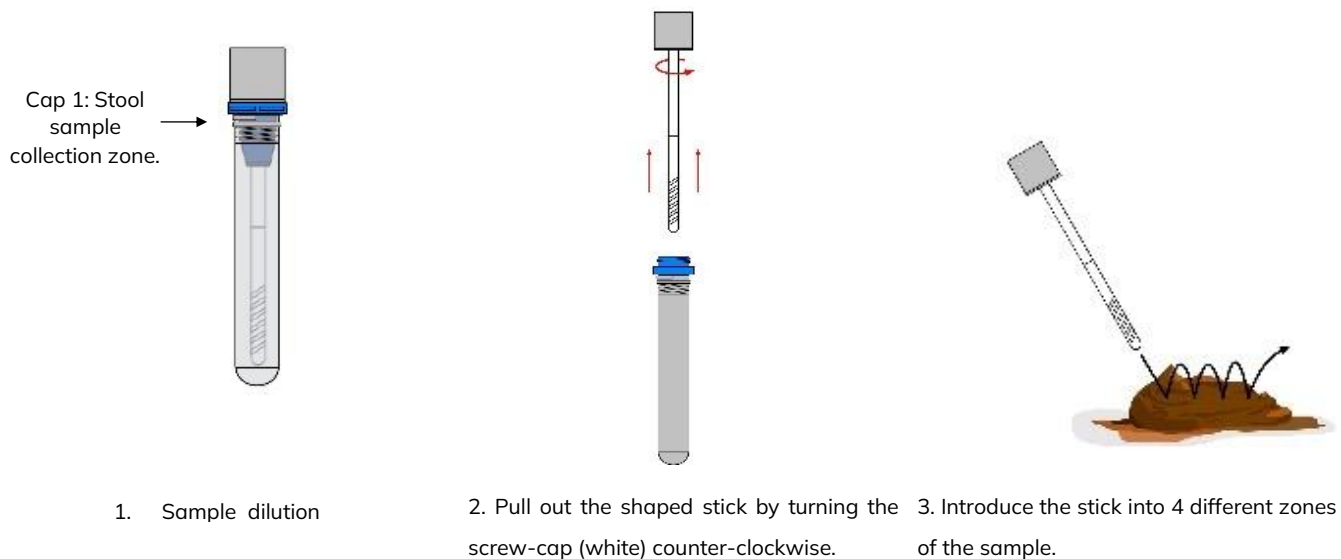
Collect a sufficient amount of stool sample (1-2 g or mL for liquid samples). Samples must be collected in a clean, dry container, without preservatives or transport media, and should be processed as soon as possible after collection. If immediate processing is not possible, fresh (undiluted) samples may be stored refrigerated at 2-8°C for up to 3 days before analysis with **FOB Turbilatex® Combo** and **Transferrin Turbilatex® Combo** reagents, or for up to 7 days before analysis with **Calprotectin Turbilatex® Combo** and **Pancreatic Elastase Turbilatex® Combo** reagents. If samples are not processed immediately, they may also be frozen at -20 °C for a maximum

of 6 months. Before testing, frozen samples must be completely thawed and brought to room. Stool samples should be homogenized thoroughly prior to preparation.

1. Sample preparation

1. Collect the stool sample in a clean, dry container.
2. Pull out the shaped stick by turning the screw-cap (white) counter-clockwise. Do not remove the blue plastic.
3. Dip the shaped stick into 4 different areas of the previously collected stool sample and repeatedly rotate the stick in order to obtain the most homogeneous sample possible, ensuring that all grooves are filled with faecal material.
4. Before placing the stick into the tube, remove any excess stool by rotating the stick against the inner wall of the container.
5. Fully insert the stick with the sample into the tube containing the extraction solution through the separator (blue). While turning the screw cap clockwise, until it is completely closed, hold the separator (blue) with the fingers to prevent it from opening. **Universal Turbilatex Sample® Vial**, containing the diluted sample, may be stored for up to 14 days refrigerated (2–8°C) or up to 3 days at room temperature, before analysis.

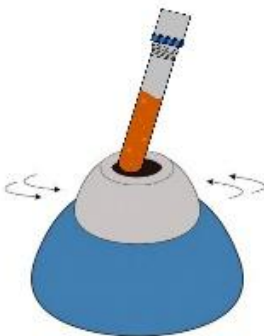
Note: For liquid samples, collection with the shaped stick may not be successful. In such cases, pipette approximately 20.00 µL of sample directly into the sample diluent contained in the **Universal Turbilatex® Sample Vial** and then continue with the extraction procedure.



Each **Universal Turbilatex® Sample Vial**, containing the sample, should be perfectly recognizable including patient's identification. In order to facilitate the identification of samples, an additional label is included for each **Universal Turbilatex® Sample Vial** in the kit.

2. Extraction Procedure

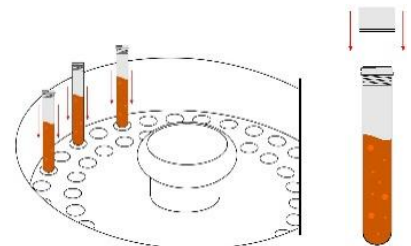
1. Bring the samples stored in a refrigerator at room temperature.
2. Shake each device by Vortex for 30-60 seconds in order to properly homogenate the content. If the grooves of the devices are visually empty of any stool material, proceed to step 3, otherwise repeat the vortexing for other 30-60 seconds. After a maximum vortexing time of 120 seconds proceed to step 3 regardless of if there is some residual stool sample in the grooves.
3. Centrifuge the tube for 10 minutes at 1000–3000 x g or allow it to stand upright for at least 15 minutes in order to remove the possible residuals of faecal material, which might damage the aspirating and dispensing systems of the automated clinical chemistry instruments. After centrifugation, remove the device from the centrifuge.
4. After the completion of the previous steps, remove the screw cap (white) and the separator (blue) from devices by rotating the separator clockwise.
5. The faecal extract is now ready to be tested. Insert the opened device directly into the clinical chemistry analyser or transfer the supernatant to an adapter cup (not provided).
6. Close the collection device by the provided additional screw cap and store or discard.



4. Shake the sample dilution vial with *diluent+sample* in order to get good sample dispersion. Use a vortex (1 minute). Centrifuge.



5. Remove both the cap and the blue separator by turning them to the opposite side.



6. Load tubes in the analyser device. Close with the additional cap

6. Limitations

- The **Universal Turbilatex® Sample Vial** is intended for the collection, dilution and preparation of human stool samples only.
- The product has no analytical measuring function and is not intended, by itself, for the detection, quantification or interpretation of any analyte.

- The device is intended for professional in vitro diagnostic use only and must be used by personnel trained in turbidimetric techniques and clinical chemistry analyzers.
- Samples must be collected in a clean, dry container, without preservatives or transport media.
- The product is a single-use device and must not be reused.
- Use of the prepared sample outside the storage conditions and time limits described in these instructions may affect sample suitability for analysis.
- The device should be used only with Turbilatex® reagents and on a compatible clinical chemistry analyzer, as specified by the manufacturer.

7. Symbols for components and reagents

	In vitro diagnostic medical device		Contains sufficient for <n> test		Catalogue number		Keep dry
	Consult electronic instructions for use		Batch code		Use-by date (yyyy-mm: year and month)		Temperature limitation
	Unique Device Identifier		Keep away from sunlight		Manufacturer		CE marking
	Do not re-use	DIL	Sample diluent				

Table 2 Symbols for IVD components and reagents.

Change log		
Version nº	Changes	Date
00	Original version	09/05/2026

Table 3 Change log.

Note: Turbilatex ® registered trademark

Nº: EUTM-010179299; (EUIPO)

Nº: 4.650.387; EEUU (UPSTO)









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