

CONTAINERS FOR SAMPLE COLLECTION

For collection, storage, and transportation of human clinical samples for subsequent examination.

Read product's instructions for use carefully before use.

Single use. Non sterile.

Product not made with natural rubber latex or dry natural rubber.

Medical device for In Vitro Diagnostic.

Intended use:

Sample collection container (flasks, tubes or kits) designed for the collection, storage and transport of human clinical specimens (as urine, sputum, faeces, etc.). The product is intended to be used for the patient to collect the urine according to the instructions for previous preparation and sample collection indicated by the health personnel or laboratory.

General precaution:

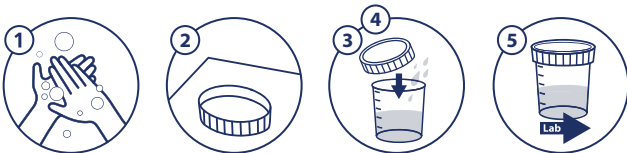
- Not suitable for any application other than its intended use.
- Do not squeeze or press the container.
- Do not use if the product or any of its components is damaged.
- Do not re-use. The re-use of this product may affect the subsequent analysis of the sample taken.
- Keep away from sunlight.
- Keep the container in a vertical position to avoid any leakage of urine, especially in the case of 2 and 3 liter containers.

Special precautions:

- ⚠ Healthcare professionals must validate the use of the container for their specific assay-instrument/reagent system combinations and specimen storage conditions.

Instructions for the patient:

1. Wash your hands and dry with paper towel.
2. Remove the lid from the container (if applicable) and place it upside down on a flat surface avoiding the inner part of the lid to contact anything, preventing its contamination.
3. Collects sample as per the facility's or facultative's instruction, considering previous preparation as indicated.
4. Deposit the specimen directly into the container and put on the lid again on the container (if applicable) to avoid contamination. In the case of kits, fill the tube and discard the rest of the urine and the collection container. Place the cap on the tube and press down to prevent future leakage.
5. Return the container or tube to the healthcare professional after sample collection.



Instructions for transport of the sample:

1. All collection devices, both containing sample or used, should be classified as biohazardous for handling and disposal purposes. It is responsibility of each laboratory to handle, treat and dispose of waste according to current legislation. Non-used containers may be considered non-hazardous and may be disposed of according to these criteria.
2. Properly label containers with patient's name, i.d., collection date and time and any additional information required by your facility's policy.

3. Properly label and package any container used to transport specimen to alternate location in accordance with applicable local and state requirements.

Instructions for sample processing:

1. Follow standard precautions when testing the sample: wear gloves, lab coat, eye protection or other personal protective equipment to protect against potential sample splashes, leaks, or possible exposure to pathogens.
2. Treat the sample according to the protocols established by your center/laboratory.
3. Discard the containers for sample collection according to your center or laboratory's protocols for discard biohazardous residues.



References:

1. Nickander, K et al. Urine culture transport tubes: effect of sample volume on bacterial toxicity of the preservative. J Clin Microbiol. 1982, 15(4):593.
2. Clinical Laboratory Standards Institute (CLSI), Urinalysis - Approved Guideline – Third Edition, GP16-A3, Wayne, PA, 2009.
3. Cabedo C, et al. ¿Es importante la técnica de recogida de la orina para evitar la contaminación de las muestras?. Aten Primaria 2004;33(3):140-4. 2003.

Symbol glossary:

REF Catalogue number	LOT Batch number	Consult instructions for use	QTY Quantity
IVD In vitro Diagnostic	Do not re-use	Do not use if package is damaged	Precaution
Keep away from sunlight	Manufacturer	Use-by-date	CE marking

In case of a serious incident* related to the product, notify to ENVASES FARMACÉUTICOS, S. A. as well as the competent authority of the State in which the user is established.

*A "serious incident" is understood as one that entails the death, or serious deterioration of the health of the patient or user or a serious threat to public health.



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