en

deltalab
member of SCGP

CONTAINERS FOR SAMPLE COLLECTION WITH INTEGRATED TRANSFER DEVICE

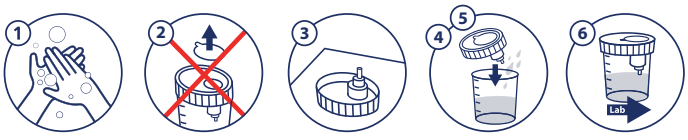
For collection, storage, and transportation of human biological fluids (urine) for subsequent examination.
Read product's instructions for use carefully before use.
Single use. Non sterile.
Product not made with natural rubber latex or dry natural rubber.
Medical device for In Vitro Diagnostic.

Intended use:
Urine collection container with an integrated transfer device designed for the collection, storage and transport of urine specimens. 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. Urine may be transferred via the integrated transfer device into an evacuated tube for transport and storage.

General precaution:
- Be careful when handling the lid of the container which is containing a needle under the label. Risk of puncture.
- Not suitable for any application other than its intended use.
- Do not squeeze or press the container.
- Do not use if package is damaged.
- Do not use if, when removing the label from the lid, the needle that forms the transfer system for sample extraction is broken or bent.
- Do not re-use. The re-use of this product may affect the subsequent analysis of the sample taken.
- Keep away from sunlight.
- Do not use if printed product information is not displayed correctly.
- Do not use if the expiry date is exceeded.
- Discard the product if it is dirty.

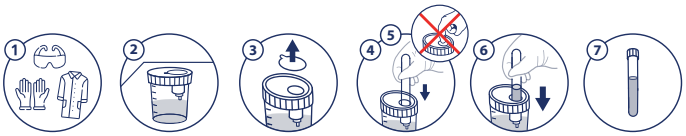
Special precautions:
Healthcare professionals must validate the use of the container for their specific assay-instrument/reagent system combinations and specimen storage conditions.

Instructions for the patient:
1. Wash your hands and then your genitals. Dry with paper tower.
2. Do not to remove the label on the cap to protect against needle puncture from the specimen transfer system.
3. Remove the lid from the container and place it upside down on a flat surface avoiding the inner part of the lid to contact anything, preventing its contamination.
4. Collect the sample as per the Health Care Professional's instructions, considering previous preparation as indicated.
5. Deposit the specimen directly into the container and put on the lid again on the container to avoid contamination.
6. Return the container to the healthcare professional after collection.
7. If you have a sample collection set or kit (which includes vacuum tube) and have been instructed by your healthcare professional to obtain the sample in the tube, follow the instructions for sample processing (from step 2).



Instructions for transport of urine specimens:
1. For transport of container to the laboratory, provide adequate warning using labelling and packaging to protect against inadvertent needlesticks caused by sharp located under label. Carefully replace label over integrated transfer device cavity. Treat the screw cap of the specimen container as a contaminated sharp. 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 tubes with patient 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, State and federal 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. Place the container upright on a flat and clean Surface. The container may be tilted if the volume of the sample is small.
3. Remove the label from the lid in order to reach the integrated transfer system of the container.
4. Place the vacuum tube with the cap facing down into the lid cavity.
5. Advance the tube over the puncture point to introduce the needle of the transfer system into the tube's cap.
6. Hold the tube in position until the tube is filled. Urine flows automatically inside the tube.
7. Remove the tube from the transfer system when full.
8. Repeat steps 4-7 for filling additional vacuum tubes and once finished, place the label in the cap cavity to reseal the cap to prevent accidental needle puncture.
9. Discard the containers for sample collection according to your center's protocols for discard biohazardous residues.



References:
1. Merritt AD, Sanford, JD. Sterile voided urine culture. J Lab Clin Med. 1958;52:463-470.
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
5. Bárcenas P, et al. Evaluación de una mejora preanalítica en urianálisis. Rev Latinoam Patol Clin Med Lab. 2017.
6. Topcuoglu C, et al. Comparison of vacuum and non-vacuum urine tubes for urinary sediment analysis. Scandinavian Journal of Clinical and Laboratory investigation, 77:8, 592-594. 2017

Symbol glossary:

REF	Catalogue number	LOT	Batch number	deltalab.es/eifus	Consult instructions for use on the website *www.deltalab.es/eifus*	QTY	Quantity
IVD	In vitro Diagnostic		Do not re-use		Do not use if package is damaged		Precaution
	Keep away from sunlight	UDI	Unique device identifier		Manufacturer		Use-by-date	CE	CE marking

en In case of a serious incident* related to the product, notify to Deltalab, S.L. 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.

CE IVD

DELTALAB, S.L.
Plaza de La Verneda 1, Pol. Ind. La Llana,
08191 Rubí, Barcelona. España/Spain.
info@deltalabgroup.com - www.deltalab.es

UPDATING DATE: 2024/10

TEC 1575 Rev.1