

TECHNICAL DATA SHEET

60 ml container for vacuum tube

code 409531

code	presentation	sterile	case qty	case weight	case vol.	cases/palet
409531	tamper evident	STERILE A	650	9.27	0.14	16

Directive 98/79/CE. "In vitro" diagnostic medical devices.



INTENDED USE - DESCRIPTION

Hospital and laboratory use, as a containment and transport container for biological fluids from the human body (urine) and subsequent in vitro analysis in combination with vacuum tubes.

Transparent polypropylene container and yellow polyethylene lid, with internal sealing ring and a molded security seal. Manufactured and assembled under aseptic conditions (sterile A).

It incorporates a cannula with an overmolded needle inside protected by a rubber cap and a transparent plastic suction nozzle. Includes a label with instructions for use and puncture precautions for a safe use.

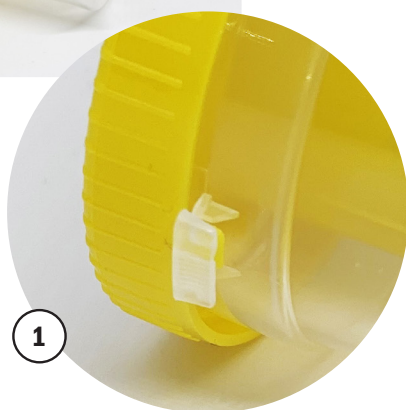
The seal closure (img.1) ensures the sterility of the inside the bottle until the moment of use, avoiding the use of an individual bag, which helps to minimize the generation of waste with the consequent lower environmental impact.



Dimensions: Ø58 mm x 51 mm



Label



1

INNOVATIVE PRODUCT
 ENVIRONMENT FRIENDLY



PATENTED PRODUCT



WRITTEN	VERIFIED	AUTHORISED
Soti Khiev Marketing Department	Anna Mir Technical, Development, Quality & Environment Director	Mónica Torras Sales & Marketing Director

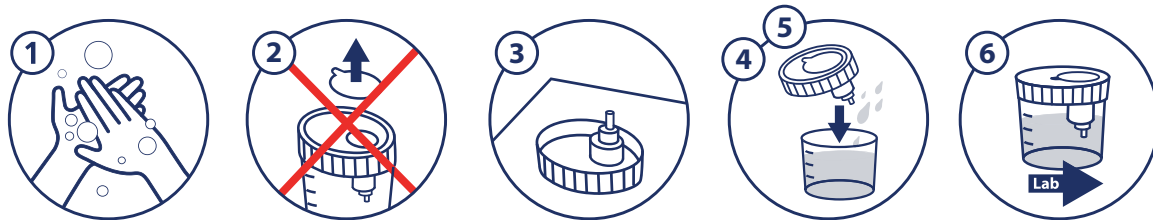
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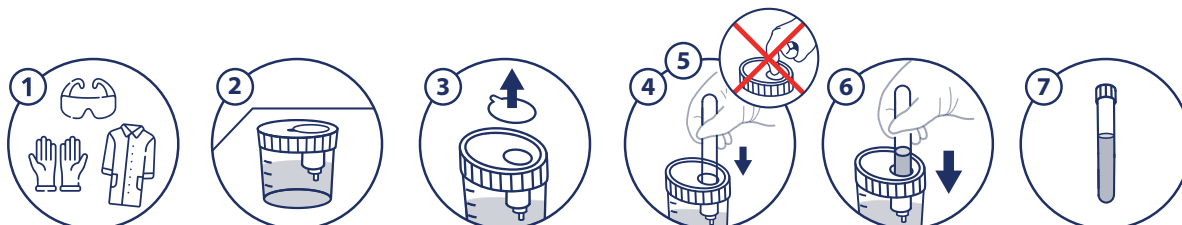
INSTRUCTIONS FOR THE SAMPLING

1. Wash your hands and then your genitals. Dry with paper towel.
2. Do not to remove the label on the cap to protect against needle puncture from the specimen transfer system.
3. Check that the container is properly closed and that the safety closure, if it exists, has not been opened, as this could compromise the sterility of the product. To open the container, turn the lid until you hear the safety lock breaking, if one exists. 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 THE 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.



You can also consult the eIFU on bit.ly/eifus and/or on www.deltalab.es

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