

BD VACUTAINER® 24 HOUR URINE COLLECTION CONTAINER WITH LONG CANNULA

For collection, storage and transportation of urine specimens.

Read product circular carefully before use.

Single use. Non sterile.

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

For *in vitro* Diagnostic Use.

Intended use:

Graduated 3-litre 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 excreted over a 24 hours for subsequent examination. Urine may be transferred via the integrated transfer device into an evacuated tube for transport and storage.

Method of collaection:


- 1) The healthcare professional obtains a container and hands it to the patient. The healthcare professional should be warned not to remove the label from the lid to avoid puncture with the needle from the specimen transfer system.
- 2) The patient removes the lid from the container, taking care not to touch anything with the long cannula of the sample transfer system.
- 3) The patient collects the sample according to the center’s instructions.
- 4) The patient deposits the sample directly into the container each time he or she urinates and replaces the lid on the container to prevent contamination.
- 5) The patient is instructed to return the container to the healthcare provider after the 24-hour urine collection.
- 6) Follow standard precautions when testing the sample: wear gloves, a lab coat, eye protection, or other personal protective equipment to protect against potential sample splashes or leaks or potential exposure to pathogens.
- 7) Place the bottle upright on a clean, flat surface. The container may be tilted if the sample volume it contains is small.
- 8) Remove the label from the lid in order to reach the integrated transfer system of the container.
- 9) Place the vacuum tube with the cap facing down into the lid cavity.
- 10) Advance the tube over the puncture point to introduce the needle of the transfer system into the cap.
- 11) Hold the tube in place until it is filled.
- 12) Remove the tube from the transfer system when it is full.
- 13) Repeat steps 4-7 to fill additional vacuum tubes, and when finished, place the label back into the cap cavity to reseal it and prevent accidental needle sticks.

Precaution:

Be careful when handling the lid of the container which is containing a needle under the label. Take care also with the transfer cannula containing the needle.

Not suitable for any application other than its intended use. Do not squeeze or press the container. Do not use if there are signs of breakage or damage to the container. Do not use if there is dirt in the container. Do not use if the needle forming the transfer system for sample collection is broken or bent when the label is removed from the cap. For single use only, for 24-hour urine collection. Do not reuse the product. Reuse of this product may affect subsequent analysis of the sample taken. Store away from light and moisture. Do not use the product if the printed information is not displayed correctly. Do not use the product if the expiration date has been exceeded. Do not use if the printed information is not displayed correctly. Do not use if the expiry date has been exceeded.

Special precautions:



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

















Transport of urine specimens:

1. For transport of the container to the laboratory, provide appropriate warning with labeling and packaging to protect against inadvertent needle sticks from the needle located beneath the label. Carefully replace the label over the cavity of the integrated transfer device. Consider the screw-top cap of the specimen container as a contaminated sharps. If a urine specimen contains blood, all specimen collection devices must be classified as biohazardous for handling and disposal purposes. It is the responsibility of each laboratory to handle, treat, and dispose of waste in accordance with applicable law. Unused containers may be considered nonhazardous and may be disposed of according to these criteria.
2. Properly label tubes with the patient name, identifier, date and time of collection, and any additional information required by your facility’s policy.
3. Properly label and package any container used to transport the specimen to another location in accordance with applicable local, state, and federal requirements.

References:

1. Kass, EH. Asymptomatic Infections of the Urinary Tract. Trans Assoc Amer Phys. 1956;6956-64.
2. Merritt AD, Sanford, JD. Sterile voided urine culture. J Lab Clin Med. 1958;52:463-470.
3. Kass EH. Bacteriuria and the diagnosis of infections of the urinary tract. Arch Intern Med. 1957;100:700-714.
4. Barry AL, et al. Laboratory diagnosis of urinary tract infections. Cumitech 2, Washington, DC: American Society for Microbiology, 1975.
5. O’Grady F, Catell WR. Kinetics of urinary tract infections. Br J Urol. 1966;38:149-151.
6. Hendman R, et al. Effect of delay on culture of urine. J Clin Microbiol. 1976;4:102-103.
7. Jefferson N, et al. Transportation delay and the microbiological quality of clinical specimen. AM J Clin Pathol. 1957;64:689-693.
8. Clinical Laboratory Standards Institute (CLSI), Urinalysis - Approved Guideline – Third Edition, GP16-A3, Wayne, PA, 2009.


Glossary of symbols:

	Catalogue number		Do not re-use		Do not use if package is damaged		Precautions
	In Vitro Diagnostic Medical Device		Manufacturer		Use-by-date		CE marking
	Keep away from sunlight		Distributor		Quantity		Unique device identifier
	Consult instructions for use on the website www.deltalabgroup.com/bd-eifus		Importer		Batch code		Swiss authorised representative

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.



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