



Evacuated Urine Collection System For In Vitro Diagnostic Use



Intended Use

VACUETTE® Urine Tubes, Urine Beakers/Cups, and Urine Transfer Devices are used together as a system for the collection, transport, processing and testing of urine in the clinical laboratory.

VACUETTE® Z Urine No Additive Tubes are used for the collection, transport, processing and testing of urine specimens for chemical urinalysis in the clinical laboratory. Conical Based Urine Tubes are used for microscopic examination of urine sediment.

The **VACUETTE® Urine Count and Culture Mannitol tube** is a urine stabilization device intended for collection, transport and storage of urine for bacterial and yeast culture. Urine samples collected in the **VACUETTE®** Urine Count and Culture, Mannitol tube can be stored at 20 - 25°C (68 - 77°F) for up to 48 h prior to culture. This device is intended for professional use only.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

VACUETTE® Urine Stabilur Tubes (*not available in USA*) are used for the collection and preservation of urine specimens for subsequent transport and analysis of urine sediment in the clinical laboratory.

Urine Beakers with ring screw closure, Urine Beakers with Safety Stopper, and Urine Beakers/Cups with Integrated Transfer Device are used to provide the means for collection and transport of urine specimens.

Urine Transfer Devices enable a clean transfer of the urine sample collected in a container directly into **VACUETTE®** Urine Tubes.

Product Description

VACUETTE® Urine Tubes are plastic tubes with a pre-defined vacuum for exact draw volumes. They are fitted with colour-coded **VACUETTE®** Safety Caps (see table below). The tubes may contain preservatives in amounts appropriate for the draw volume based on pre-defined vacuum in the tube. All products of the Urine Collection System are to be used by appropriately trained healthcare professionals only in accordance with these instructions.

VACUETTE® Safety Cap Colour Codes

Description	Safety Cap Colour	Cap Inner Ring Colour
Z Urine No Additive Tubes		
Round Base	yellow	yellow
Conical Base	yellow	yellow
Urine Count and Culture Mannitol tubes (CCM; IFU 980246)		
Round Base	yellow	black
Conical Base	yellow	black
Urine Stabilur Tubes – not available in USA		
Round Base	yellow	red
Conical Base	yellow	red

VACUETTE® Z Urine No Additive Tubes

VACUETTE® Z Urine No Additive Tubes are sterile, leak-proof and made of clear unbreakable disposable plastic. If the specimen cannot be tested within two hours of collection, it should be refrigerated (2-8°C) per CLSI GP16-A3 Guideline.

VACUETTE® Urine Count and Culture Mannitol tubes (CCM)

VACUETTE® Urine CCM tubes are made of PET with a pre-defined vacuum for nominal draw volumes. They are fitted with yellow **VACUETTE®** Safety Pull Caps. The tube interior is sterile. The evacuated tube contains a stabilizer to preserve the urine sample by preventing bacterial and yeast growth. **Follow the IFU 980246.**

VACUETTE® Urine Stabilur Tubes – not available in USA

VACUETTE® Urine Stabilur Tubes are made of PET with a pre-defined vacuum for nominal draw volumes. They have yellow **VACUETTE®** Safety Pull Caps and a sterile interior. The evacuated tube contains an additive for the stabilization of formed elements present in urine sediment, such as casts, crystals, white blood cells and red blood cells.

Urine Beakers with ring screw closure are sterile plastic beakers that feature an integrity seal, which ensures integrity and sterility of the interior until the lid is opened. The beakers are leak-proof (with manual transport).

Urine Beakers with Safety Stopper are sterile plastic beakers with a cross cut in the stopper of the lid.

Urine Beakers with Integrated Transfer Device are plastic beakers that are available as sterile and non-sterile versions. The lid contains an off-centered integrated transfer device. The beakers are leak-proof (with manual transport).

Urine Cups with Integrated Transfer Device are plastic cups that are available as sterile and non-sterile versions. The lid contains a centered integrated transfer device. The beakers are leak-proof (with manual transport).

Urine Transfer Device

The Urine Transfer Device is a plastic holder containing a needle and a straw which allows the transfer of the urine sample collected in a container directly into **VACUETTE®** Urine Tubes. The straw is available in two lengths (8cm and 16cm), the shorter is available as sterile and non-sterile versions and the longer is available as non-sterile. The longer version is not available in the USA.

Storage before use

Store tubes and Urine Cups with Integrated Transfer Device at 4-25°C (40-77° F).

NOTE: Avoid exposure to direct sunlight. Exceeding the maximum recommended storage temperature may lead to impairment of the tube quality (i.e. vacuum loss, colouring, etc.).

Precautions/Cautions

- Do not reuse, products are for single use only.
- Do not use any products after expiration date.
- Do not use any products that are contaminated and contain foreign particles.
- Handle all biological specimens and collection devices according to the policies and procedures of your facility.
- Obtain appropriate medical attention in the case of exposure to biological specimens, as these specimens may transmit infectious diseases.
- Discard all collection devices in biohazard containers that are approved for their disposal.
- For analysis with flow cytometry ensure that the additive in the tube is completely dissolved, otherwise retesting may be necessary if increased results occur due to undissolved particles.
- The tube's preservative is a white powder. Do not use if it is discoloured.
- If a blank value is necessary, it is recommended that the value is measured for each tube lot.
- The perforated label of the Urine Cup with Integrated Transfer Device (which has a centered integrated transfer device) serves as a sterility integrity seal.
- To avoid needle stick injuries, never insert fingers into the (integrated) Urine Transfer Device.
- Prior to any transport ensure that the Urine Beaker/Cup is completely closed.
- Urine Beakers/Cups are not suitable for transport via pneumatic transport systems.

Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.

Directions for Use

READ THIS ENTIRE DOCUMENT BEFORE PERFORMING URINE COLLECTION.

Equipment required for urine collection

Ensure that the following materials are readily accessible before performing urine collection:

1. Urine Beaker/Cup and Urine Transfer Device if necessary.
2. All necessary tubes, identified for size, shape, draw and preservative.
3. Labels for positive patient identification of samples.

NOTE: Instructions for handling and storage appropriate for the necessary testing of the urine sample should be provided to personnel involved in specimen collection.

I. Collection of the mid-stream urine specimen

Control that the perforated label has not been torn before handing in the Urine Cup with Integrated Transfer Device to the patient. If the label has been torn, the sterility of the product cannot be guaranteed. Indicate the patient not to remove the label to protect him against needle stick injuries.

NOTE: For Urine Beakers/Cups with Integrated Transfer Device the fill level should be between 20ml (40ml when collecting more than one tube) and 100ml. Urine Beakers with ring screw closure and Urine Beakers with Safety Stopper should be 2/3 full.

Patients should be directed to follow the steps below in order to collect a "clean catch" mid-stream urine sample in an appropriate Urine Beaker/Cup as accepted or validated by your facility:

1. Thoroughly wash the hands and then clean the genital region.
NOTE: For Urine Beakers/Cups with Integrated Transfer Device caution patient not to remove the safety label on the lid to protect against needle sticks from the "sharp" contained in the integrated transfer device.
2. Open the lid of the beaker/cup by turning it in an anti-clockwise direction. For the Urine Cup with Integrated Transfer Device (which has a centered integrated transfer device) the label separates along the perforated line when the lid is opened. Place the lid with the inside facing upwards on a stable surface. Ensure that the inside of the lid is not touched or contaminated in any way.
3. After a small quantity of the initial urine flow is released into the toilet, fill the Urine Beaker/Cup without breaking the stream. Any remaining urine should be released into the toilet.
4. Close the lid of the Urine Beaker/Cup by turning it in a clockwise direction until it is firmly closed to prevent leakage. Take care not to contaminate the inside of the lid.
5. Pass the closed Urine Beaker/Cup to responsible healthcare professional immediately.

II. Instructions for transferring the urine specimen into VACUETTE® Urine Tubes

WEAR GLOVES WHEN HANDLING URINE COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

NOTE: For VACUETTE® Urine Count and Culture Mannitol tubes (CCM) follow IFU 980246.

1. Consider the following points when transferring samples to VACUETTE® Urine Tubes:
When using a Urine Beaker with ring screw closure:
 - a. Open the beaker.
 - b. Submerge the tip of the Urine Transfer Device into the urine specimen.When using Urine Beakers with Safety Stopper
 - a. Do not open the beaker.
 - b. Submerge the tip of the transfer device into the specimen by pushing the tip through the cross cut in the stopper of the lid.When using a Urine Beaker with Integrated Transfer Device (which has an off-centered integrated transfer device):
 - a. Do not open the beaker.
 - b. Peel back the safety label on top of the beaker to expose the Integrated Transfer Device.When using a Urine Cup with Integrated Transfer Device (which has a centered integrated transfer device):
 - a. If more than one tube will be filled, loosen the lid (by turning it in an anti-clockwise direction) slightly more than a quarter turn to normalize the pressure inside the cup.
 - b. Peel back the safety label on top of the cup to expose the Integrated Transfer Device.
2. Insert the VACUETTE® Tube into the (integrated) Urine Transfer Device with the safety cap down. Ensure that the needle is fully piercing the stopper of the urine tube. Urine will flow into the tube automatically in accordance to the pre-defined vacuum.

If no urine flows into the tube or if urine flow ceases before an adequate sample is collected, the following steps are suggested to complete satisfactory collection:

- a. Push the tube down until the tube cap has been fully pierced. Always hold in place by pressing the tube with the thumb to ensure complete vacuum draw.
- b. If urine still does not flow, remove the tube and place a new tube into the transfer device.
3. Hold the tube in position until urine stops flowing. If multiple tubes are to be collected including urine culture tubes, the urine culture tubes must be collected first.
4. Remove the tube from the transfer device. **VACUETTE®** Urine Stabilur tubes should be inverted several times (8-10x) to ensure a homogeneous mixing of the urine sample and preservative.
5. When using a Urine Beaker with ring screw closure:
Close the lid of the beaker.
When using a Urine Beaker with an Integrated Transfer Device (which has an off-centered integrated transfer device):
Put the safety label back onto the lid to reseal the Integrated Transfer Device.
When using a Urine Cup with Integrated Transfer Device (which has a centered integrated transfer device):
 - a. Put the safety label back onto the lid to reseal the Integrated Transfer Device.
 - b. Please be sure to completely close the lid of the cup again (by turning it in a clockwise direction).
6. Dispose of the Urine Transfer Device and the Urine Beaker/Cup by following the general hygiene guidelines and legal regulations of your facility.
7. The patient and the patient's urine specimen must be positively identified at the time of collection. The sample must be labelled immediately following collection and mixing.
8. Transport to laboratory immediately.
9. Proper storage and preservation of urine samples should be ensured during the entire process.

Centrifugation

Ensure that tubes are properly seated in the centrifuge carrier; incomplete seating could result in the separation of the **VACUETTE®** Safety Cap from the tube.

VACUETTE® Urine Tubes are recommended to be centrifuged at 400g for a period of 5 minutes. Centrifugation should be done at ambient temperature of 15°C-24°C (59°F-77°F)

Freezing and thawing

Filled **VACUETTE®** Urine Tubes withstand freezing down to -20°C. It is recommended to place the tubes upright in an open metal rack and to keep the tubes in the refrigerator (4-8°C) for 2 hours prior to freezing at -20°C. Thawing is recommended at room temperature or in the refrigerator.

NOTE: This procedure is only recommended if the analyte to be determined allows freezing of the urine sample. Refer to the instrument assay instructions for use for information on the correct storage and stability of the sample.

Recommendations to maintain stability of sample quality:

1. In cases where the sample remains in the Urine Beaker/Cup for longer than 1 to 2 hours, the sample should be thoroughly mixed by swirling the beaker/cup, or by stirring the sample with the urine transfer device to redistribute the sediments throughout the sample prior to transferring.
2. Exclusive use of sterile Urine Beakers/Cups for urine collection will reduce possible contamination with microorganisms.
3. It is recommended that urinalysis be performed within 2 hours of collection. If testing is delayed, refrigeration for some chemical components may be adequate. Refrigeration may be an acceptable means of inhibiting bacterial growth, but the sample should be inspected for crystal formation, which may be induced by refrigeration. Otherwise, urine specimens must be properly preserved. Preservatives may be used for bacteriology, however, if your sample is so small that the crystals will not dissolve, a plain (without additive) tube is recommended.

VACUETTE® Safety Caps

The **VACUETTE®** Urine Collection System features a unique safety cap design. There are two different closure systems available depending on the size of the tube:

13mm tubes:

Premium tubes: Remove the cap from the tube by twisting in an anti-clockwise direction. The cap cannot be removed by a simple pull action.

Non-ridged tubes: Removed the cap by a simple pull action.












16 mm tubes:

Non-ridged tubes: Remove the cap from the tube with a simple pull action.

Disposal

- The general hygiene guidelines and legal regulations for the proper disposal of infectious material should be considered and followed.
- Disposable gloves prevent the risk of infection.
- Contaminated or filled urine collection tubes must be disposed of in suitable biohazard disposal containers, which can then be autoclaved and incinerated.

Label Information

	Manufacturer		Temperature limit		Do not re-use
	Use-by date		Consult instructions for use		Warning for needlestick injuries
	Batch code		Sterilized using irradiation		Do not use if package is damaged and consult instructions for use
	Catalogue number		In vitro diagnostic medical device		

Standards : ISO 11137, EN 556-1, EN 14254

Reference : Clinical Laboratory and Standards Institute (CLSI): GP16-A3 Urinalysis; Approved Guideline – Third Edition. 2009.