



## Evacuated Urine Collection System For In Vitro Diagnostic Use



### Intended Use

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

### 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 various amounts dependent on the amount of pre-defined vacuum in the tube. **VACUETTE®** Urine Tubes, **VACUETTE®** Urine Sets and Urine Beakers are hermetically sealed and virtually unbreakable. Tubes and beakers interiors are sterile.

### VACUETTE® SAFETY Cap Colour Codes

Description	SAFETY Cap Colour	Cap Inner Ring Colour
<b>Urine Tubes without Preservative</b>		
Round Base	yellow	yellow
Conical Base	yellow	yellow
<b>Urine Tubes with Preservative</b>		
Round Base	yellow	black
Conical Base	yellow	black

### VACUETTE® Urine Tubes

**VACUETTE®** Urine Tubes are used as collection containers and/or transport containers. The tubes are sterile, leak-proof and made out of clear unbreakable disposable plastic. **VACUETTE®** Urine Tubes are used for chemical urinalysis. Conical Based Urine Tubes are used for microscopic examination of urine sedimentation.

### VACUETTE® Urine Tubes with Preservative

**VACUETTE®** Urine Tubes with preservative are used as collection containers and/or transport containers. The tubes are sterile, leak-proof and made out of clear unbreakable disposable plastic. **VACUETTE®** Urine Tubes with preservative are used for specimens not analysed within 2 hours of collection, specimens being tested for an otherwise unstable analyte, or specimens being stabilized for microbiological studies.

### VACUETTE® Urine Beakers

**VACUETTE®** Urine Beakers are used to provide the means for collection of urine specimens. The beakers are sterile, break-proof and leak-proof according to OENORM.

### VACUETTE® Urine Transfer Device

The Urine Transfer Device enables a clean transfer of the urine sample directly into **VACUETTE®** Urine Tubes.

### VACUETTE® URINE COLLECTION SYSTEM Handling Procedures

#### Storage guidelines for tubes before use

Store tubes 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.) Filled tubes can be stored at down to -20°C.

### VACUETTE® Precautions/Cautions

#### Precautions

- Do not use tubes/beakers if foreign matter is present.

#### Caution

Handle all biological specimens and collection devices (**VACUETTE®** Urine Beaker, **VACUETTE®** Urine Transfer Device) 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.
- The preservative is a white powder. Do not use if it is discoloured.
- For analysis with flow cytometry, double determination may be required in cases of increased results due to undissolved particles.
- Do not use tubes after expiration date.
- Do not use tubes/beakers which are contaminated and contain foreign particles.
- Beakers are not suitable for transporting via pneumatic post (According to BS EN 14 254)
- To avoid needle stick injuries, never insert fingers into the Urine Transfer Device

### Equipment required for urine collection

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

- Urine Beaker and Urine Transfer Device if necessary.
- All necessary tubes, identified for size, draw and preservative.
- Labels for positive patient identification of samples.

## General instructions

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING URINE COLLECTION:

**NOTE:** Proper handling of urine specimens is important to avoid deterioration of constituents. Urine specimens are often collected and handled by personnel outside the laboratory. Education or documented instructions to improve the collection and handling of specimens should be provided to personnel involved in specimen collection. Written or graphic instructions should be provided for the proper collection of a clean voided urine specimen. These instructions should be made available to anyone collecting specimens in a hospital or other facility. Written or graphic instructions should also be provided for the proper collection of timed specimens. The instructions should include the proper storage and preservation of urine when specimens are being collected for special tests.

### I. Directions for the patient

Patients should be directed to follow the following steps in order to collect a “clean catch” mid-stream urine sample in an appropriate sterile urine beaker:

When using a Urine Beaker and/or a Urine Beaker with a stopper:

- a. Thoroughly wash the hands and then the genital region. Wipe dry with paper towel.
- b. Open the lid of the Urine Beaker by turning it in an anti-clockwise direction. Place the lid of the Urine Beaker with the inside facing upwards in a hygienic place. Please ensure that the inside of the lid is not touched or contaminated in any way.
- c. After a small quantity of the initial urine flow is released into the toilet, fill the urine sample beaker until it is 2/3 full, without breaking the stream. Any remaining urine should be released into the toilet.
- d. Firmly close the lid of the urine beaker by turning in a clockwise direction to prevent leakage. Take care not to contaminate the inside of the lid.
- e. Pass the firmly closed urine beaker and its contained sample to the responsible person immediately.

When using a Urine Beaker with an Integrated Transfer Device:

- a. Thoroughly wash the hands and then the genital region. Wipe dry with paper towel.  
**NOTE:** 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.
- b. Open the lid of the Urine Beaker by turning it in an anti-clockwise direction. Place the lid of the Urine Beaker with the inside facing upwards in a hygienic place. Please ensure that the inside of the lid with the integrated transfer device is not touched or contaminated in any way.
- c. After a small quantity of the initial urine flow is released into the toilet, fill the urine sample beaker without breaking the stream. Any remaining urine should be released into the toilet.  
**NOTE:** In an open beaker, the minimum fill level should be 20ml; and the maximum fill level should be 90ml.
- d. Firmly close the lid of the urine beaker by turning in a clockwise direction to prevent leakage. Take care not to contaminate the inside of the lid and/or the integrated urine transfer device.
- e. Pass the firmly closed urine beaker and its contained sample to the responsible person immediately.

### II. Processing of Specimen

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

- Select the tube or tubes appropriate for required specimen.
  - Select a Urine Transfer Device when using Urine Beaker and/or Urine Beaker with stopper.
  - Disposal Container for safe disposal of used Urine Transfer Device.
1. Prepare the Urine Beaker and its contained sample for **VACUETTE**<sup>®</sup> Urine Tube collection.

When using a Urine Beaker:

Open the beaker. Submerge the tip of the Urine Transfer Device into the urine specimen.

When using a Urine Beaker with a stopper:

Do not open the beaker. Submerge the tip of the transfer device into the specimen by pushing the tip through the cross cuts in the stopper of the lid.

When using a Urine Beaker with an Integrated Transfer Device:

Do not open the beaker. Peel back the safety label on top of the beaker to expose the integrated transfer device. After urine collection place the label back over the hole to reseal it.

**NOTE:** In a closed beaker, the minimum fill level should be 20ml when sampling only one tube; and 40ml when sampling more than one tube. The maximum fill level should be 100ml.

2. Insert the **VACUETTE**<sup>®</sup> Tube into the urine transfer device / transfer device of Beaker with integrated transfer device with the safety cap down. Ensure that the needle penetrates the stopper of the urine tube. Urine will flow automatically in accordance to the pre-defined vacuum within the tube.  
If no urine flows into the tube or if urine flow ceases before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:
  - a. Push the tube forward until the tube cap has been fully penetrated. 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 in position until urine stops flowing into the tube. If multiple specimens are to be collected including urine culture tubes, the urine culture tubes must be drawn first.
4. Remove the tube from the transfer device. Urine tubes with preservative should be inverted several times (8-10x) to ensure a homogeneous mixing of the urine sample and preservative.
5. Dispose of the urine sample transfer device and the urine beaker in a biohazard container approved by your facility.
6. The patient and the patient’s urine sample must be positively identified at the time of collection. The specimen must be labeled immediately following collection and mixing.
7. Transport to laboratory immediately.

### III. Centrifugation

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

**VACUETTE**<sup>®</sup> 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)

### Recommendations to maintain stability of sample quality:

1. In cases where the sample remains in the urine beaker for longer than 1 to 2 hours, the sample should be thoroughly mixed by swirling the beaker, or by stirring the sample with the urine transfer device to redistribute the sedimentation throughout the sample prior to transferring.
2. Exclusive use of a sterile urine beaker for urine collection will delay bacterial growth, which in turn could influence sample quality.
3. It is recommended that urinalysis be performed within 2 hours of collection. If testing is delayed, refrigeration is for some chemical components 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) or 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 tube is recommended.

### VACUETTE® Safety Caps










The VACUETTE® Urine Collection System features a unique safety cap design to minimize aerosol generation.

VACUETTE® Safety Grip Caps have a diameter of 16mm – remove the cap from the tube with a simple pull action or VACUETTE® Safety Grip Caps with a diameter of 13mm - remove the cap from the tube by twisting in an anti-clockwise direction with a twist-pull motion.

### 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
	Use-by date		Consult instructions for use
	Batch code		Sterilized using irradiation
	Catalogue number		Sterilized using ethylene oxide
	Do not re-use		

Standards :

ISO 11137, ISO 11135, EN 556

Literature :

CLSI GP16-A3 Urinalysis ; Approved Guideline – Third Edition

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