VACUETTE®

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VACUETTE® Urine Count and Culture Mannitol tube (CCM)

For In Vitro Diagnostic Use

EN

Intended Use

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.

Product description

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.

VACUETTE® Urine CCM Tube Handling Procedures

1. Allow the tube to fill until the vacuum is depleted and filling stops. A 10% fill tolerance is allowed. This guarantees the correct (pre-defined) urine to additive ratio. Significant under-filling of the tube can influence urine cultures, leading to erroneous results.
2. Gently invert the tube at least 5 times to mix the urine sample with the additive.
3. Follow the recommended guidelines from your facility when transporting the specimens to a different location. Tubes should always be properly labelled and packaged during their transport.

Storage guidelines for tubes before use

Store tubes at 4 - 25°C (40 - 77°F).

***NOTE**: Avoid exposure to direct sunlight. Exceeding the maximum or the minimum recommended storage temperature may lead to impairment of the tube quality (e.g. accelerated vacuum loss).*

Precautions/Cautions

- For *in vitro* diagnostic use only.
- For single use only.
- Personal protective equipment such as gloves and laboratory gowns should be used to protect from potential exposure to pathogens and infectious materials.
- 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.
- Do not use tubes after expiration date.
- During the specimen collection, do not use tubes/beakers which are contaminated and contain foreign particles.
- Ensure a homogeneous mixing of the urine sample and preservative after collecting the specimen.
- The microbial stability at room temperature cannot be ensured for up to 48 hours when the urine collected in the CCM tube is diluted.
- The product is to be used by appropriately trained healthcare professionals only in accordance with these instructions.
- To avoid needle stick injuries, never insert fingers into the Urine Transfer Device and Urine Beaker with Integrated Transfer Device.
- Removal of the cap from the tube will compromise its sterility, therefore it is not recommended to manually fill a **VACUETTE®** Urine CCM tube.

Safety Caps

VACUETTE® Safety Pull Caps are available for CCM non-ridged tubes with diameters of 13 mm and 16 mm. The caps can be removed with a simple pull action.

Disposal

- The general hygiene guidelines and legal regulations for the proper disposal of potentially infectious material should be considered and followed.
- Disposable gloves should be worn to avoid the risk of infection.
- Contaminated or filled urine collection tubes shall be disposed of in suitable biohazard disposal containers.

Materials Not Provided

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

- Urine beaker and urine transfer device or urine beaker with an integrated transfer device.
- Labels for positive patient identification of samples.
- Growth medium and supplies for microorganisms culture and identification

Directions for Use

Collection of the mid-stream urine specimen

Patients should be directed to follow the following steps in order to collect a “clean catch” mid-stream urine sample in an appropriate Urine Beaker, as accepted or validated by your facility:

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.

Instructions for transferring the urine specimen into the VACUETTE® Urine CCM tube

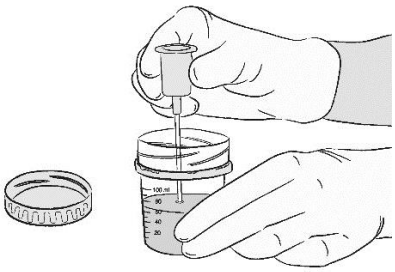
WEAR GLOVES WHEN HANDLING URINE COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

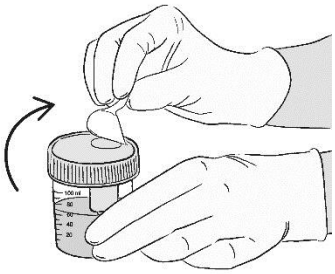
Be sure that the following materials are readily accessible before processing the specimen:

- Required **VACUETTE®** Urine CCM tube.
- Urine Transfer Device (when using Urine Beaker and/or Urine Beaker with Stopper).
- Sharp container for safe disposal of used Urine Transfer Device.

1. Prepare the Urine Beaker and its contained sample for collection:

When using a Urine Beaker:	When using a Urine Beaker with a Stopper:	When using a Urine Beaker with an Integrated Transfer Device:
Open the beaker. Submerge the tip of the Urine Transfer Device into the urine specimen.	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.	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.

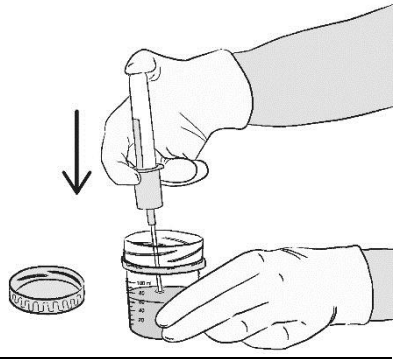


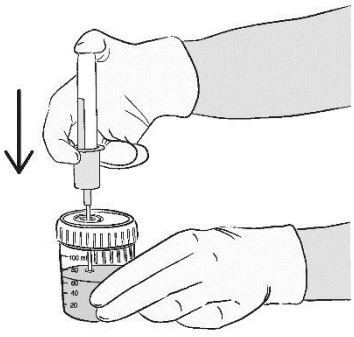


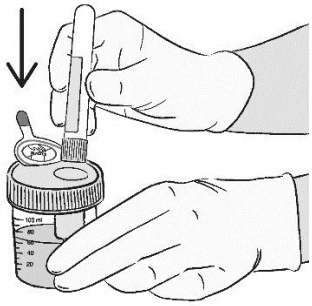
NOTE*: In a closed beaker, the minimum fill level should be 20ml when sampling only one tube; and 40ml when sampling more than one tube. The maximum fill level should be 100ml.*

2. Insert the **VACUETTE®** Urine CCM 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.

When using a Urine Beaker:	When using a Urine Beaker with a Stopper:	When using a Urine Beaker with an Integrated Transfer Device:

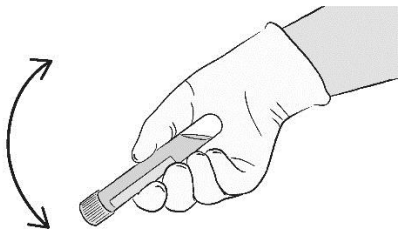






If no urine flows into the tube or if urine flow ceases before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:

   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.
4. Remove the tube from the transfer device. **VACUETTE®** Urine CCM tubes should be inverted at least 5 times to ensure a homogeneous mixing of the urine sample and preservative:



≥ 5X

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 labelled immediately following collection and mixing.
7. Transport to laboratory immediately.

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.*

Processing

- 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.
- Follow the recommended procedures from the laboratory of your facility for properly processing the urine contained in **VACUETTE**® Urine CCM tubes when performing a urine culture.

Limitations

- The volume of specimen drawn in a tube can vary depending on different physical factors, such as the altitude at which the specimen was transferred into the tube, the temperature, the remaining shelf life of the product and the filling procedure.
- Samples must be filled to the indicated fill line to guarantee the correct (pre-defined) urine to additive ratio.

Performance characteristics

The performance characteristics of the **VACUETTE**® Urine CCM tube were determined using recovery of microorganisms determined to cause urinary tract infections. Inoculation and recovery of the microorganisms studied were outlined in the Clinical Laboratory Standards Institute (CLSI) M40-A2 document. The list of microorganisms listed below (acquired from ATCC) were evaluated in this study. To perform viability studies, microorganisms were diluted down from 1.5 x 10^8 CFU/mL (equivalent to a 0.5 McFarland standard), then spiked into pooled filter sterilized urine to get final concentrations of 1.5 x 10^4, 1.5 x 10^3 and 1.5 x 10^2. The spiked urine was then placed in their respective **VACUETTE**® Urine CCM tube and stored for 0, 24, 48 hours at room temperature (20 – 25°C/68 – 77°F) and at refrigerated temperature (2 – 8°C/36 – 47°F); at the designated time intervals the **VACUETTE**® Urine CCM tubes were removed and processed. The acceptance criteria are no more than +/-1 log from the original spiked concentration.

Microorganisms:
Escherichia coli (ATCC® 25922)
Enterococcus faecalis (ATCC® 29212)
Proteus mirabilis (ATCC® 7002)
Pseudomonas aeruginosa (ATCC® BAA-427)
Staphylococcus saprophyticus (ATCC® 15305)
Enterobacter cloacae (ATCC® 13047)
Klebsiella pneumoniae (ATCC® 13883)
Streptococcus agalactiae (ATCC® 13813)
Candida albicans (ATCC® 24433)
Candida glabrata (ATCC® 2001)

VACUETTE® CCM tubes were able to maintain viability of microorganisms for the claimed time of 48h at both room temperature (20 – 25°C/68 – 77°F) and at refrigerated temperature (2 – 8°C/36 – 47°F).

Microorganism	Hold Temperature	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 48 hrs	T=48 hrs Log reduction (-) Log increase (+)
Escherichia coli	2-8°C	7.0×10^3	4.0×10^3	-0.39
	20-25°C	6.9×10^3	3.7×10^3	-0.27
Enterococcus faecalis	2-8°C	6.9×10^3	6.5×10^3	-0.03
	20-25°C	6.0×10^2	2.8×10^3	0.56
Proteus mirabilis	2-8°C	2.0×10^3	1.5×10^3	-0.11
	20-25°C	2.0×10^3	1.4×10^3	-0.14
Pseudomonas aeruginosa	2-8°C	6.3×10^3	4.8×10^3	-0.11
	20-25°C	6.5×10^2	2.4×10^2	-0.44
Staphylococcus saprophyticus	2-8°C	6.1×10^3	2.6×10^3	-0.38
	20-25°C	6.2×10^3	3.7×10^3	-0.23
Enterobacter cloacae	2-8°C	1.0×10^3	3.4×10^2	-0.49
	20-25°C	1.3×10^4	2.4×10^3	-0.73
Klebsiella pneumoniae	2-8°C	6.4×10^3	5.2×10^3	-0.09
	20-25°C	7.0×10^3	5.9×10^3	-0.08
Streptococcus agalactiae	2-8°C	7.9×10^3	4.4×10^3	-0.25
	20-25°C	7.1×10^3	4.9×10^3	-0.16
Candida albicans	2-8°C	1.9×10^3	7.4×10^2	-0.43
	20-25°C	1.8×10^3	3.0×10^2	-0.78
Candida glabrata	2-8°C	3.5×10^3	1.6×10^3	-0.34
	20-25°C	4.2×10^4	1.6×10^4	-0.44

0.5 McFarland microorganism suspension was diluted and spiked into clinically negative urine. 100µL of spiked urine was plated on each plate.

Label Information

	Manufacturer		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Catalogue number		*In vitro* diagnostic medical device
	Sterilized using irradiation	Rx only	Prescription Device

References

Clinical Laboratory and Standards Institute (CLSI): GP16-A3 Urinalysis Approved Guideline – Third Edition. 2009.
Clinical Laboratory and Standards Institute (CLSI): M40-A2 Quality Control of Microbiological Transport Systems; Approved Standard-Second Edition. 2014
European Urinalysis Guidelines : Scand J. Clin. Lab. Invest 2000 ; 60 : 1 – 96.
Standards for Sterilization: ISO 11137.

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