

BD Vacutainer® Urine Products

For collection, storage, and transport of urine specimens. Sterile except as noted.

Urine Products are not made with natural or dry rubber latex.













REF 364915	REF 364917	REF 364918	REF 364920	REF 364938	REF 364940	REF 364941	REF 364943
REF 364944	REF 364946	REF 364953	REF 364954	REF 364955	REF 364956	REF 364957	REF 364958
REF 364959	REF 364981	REF 364989	REF 364990	REF 364991	REF 364992	REF 365000	REF 365017
REF 365307	REF 365309	REF 368500	REF 368501	REF 368832			

BD Vacutainer® Urine Products

Urine Collection Cups

Urine Transfer Straws

Urinalysis Conical Urine Tubes, No Additive, 8.0 mL / 9.5 mL, 16 x 100 mm Urinalysis Urine Tubes, No Additive, 10.0 mL, 16 x 100 mm

Urinalysis Preservative Conical Urine Tubes, 8.0 mL, 16 x 100 mm

Urinalysis Preservative Urine Tubes, 8.0 mL, 16 x 100 mm

C&S Preservative Urine Tubes, 4.0 mL, 13 x 75 mm

C&S Boric Acid Sodium Borate/Formate, 4.0 mL, 13 x 75 mm

C&S Preservative Glass Urine Tubes, 5.0 ml, 16 x 75 mm**

C&S Preservative Glass Urine Tubes, 10.0 mL, 16 x 100 mm**

**Only available in kit format.

BD Vacutainer® Urine Collection Kits Product Descriptions

BD Vacutainer® Urine Products are available in various kit formats:

- Urine Transfer Straw Kit A kit composed of a Urine Transfer Straw with a C&S Preservative Tube or Urinalysis Tube.
- Urine Cup Kit A kit composed of a Urine Collection Cup with either a C&S Preservative Tube and a Castile Soap Towelette, or a Urinalysis Tube.
- Urine Complete Cup Kit A kit composed of a Urine Collection Cup, C&S Preservative Tube, a Urinalysis Tube, and a Castile Soap Towelette.

BD Vacutainer® Urine Collection Cup Kits with C&S Preservative Tubes have Castile Soap Towelettes. These towelettes are supplied for cleansing the genitourinary area prior to collecting a clean-catch, midstream urine specimen. Please refer to your facility's recommended procedures for collection and transfer of urine specimens.

BD Vacutainer® Urine Collection Cup and Urine Transfer Straw **Product Descriptions**

- BD Vacutainer® Urine Collection Cup is a plastic cup with a sterile interior, graduated to indicate a volume of up to 4.5 oz or 120 mL of urine. It is closed with a screw cap containing an integrated transfer device. The sterile interior is maintained until the cup lid is removed for urine collection. Store cup between 4–35 °C.
- BD Vacutainer® Urine Transfer Straw is a non sterile, plastic holder device that contains a needle with a straw attachment that can be used with most urine collection cups to fill evacuated tubes.

Intended Use of BD Vacutainer® Urine Collection Cup and Urine Transfer Straw

- 1. Urine collected into the BD Vacutainer® Urine Collection Cup (cup) may be transferred via the integrated transfer device into an evacuated tube for transport and storage. In addition, the cup may be used to transport the entire specimen, provided adequate packaging and labeling is used.
- 2. Urine collected into an alternate container may be transferred via the BD Vacutainer® Urine Transfer Straw into an evacuated tube for transport and storage.

Limitations of BD Vacutainer® Urine Collection Cup and Urine Transfer Straw

- 1. There is no preservative present in the cup. Specimens not tested or preserved within 1–2 hours of collection should be refrigerated.
- 2. Due to the dead space in the cup, approximately 2.25 mL of the urine specimen will be unavailable in the cup resting on a flat surface. The cup may be tilted to fill the tube, and then approximately 0.6 mL of the urine specimen will be unavailable.

BD Vacutainer® Urine Tubes

Provide a safe method for direct sampling of urine specimens from the BD Vacutainer® Urine Collection Cup. The tubes have sterile interiors.

BD Vacutainer® C&S Preservative Urine Tubes for Culture and Sensitivity **Product Descriptions**

BD Vacutainer® C&S Preservative Urine Tubes and BD Vacutainer® C&S Boric Acid Sodium Borate/Formate tubes have a 4.0 mL draw volume, $13 \times 75 \text{ mm}$ with a lyophilized maintenance formula and a light gray stopper and BD Vacutainer® PC&S Boric Acid Sodium Borate/Formate tubes have a BD Hemogard™ closure with olive shield color. A minimum fill line of 3.0 mL is indicated on the label.

The mean concentration of the preservative in the urine sample in BD Vacutainer® C&S Preservative Urine Tubes is:

Boric Acid 2.63 mg/mL

Sodium Borate 3.95 mg/mL

Sodium Formate 1.65 mg/mL

BD Vacutainer® C&S Preservative Glass Urine Tubes have a 5.0 mL draw volume, 16 x 75 mm with a lyophilized maintenance formula and a gray stopper. A minimum fill line of 4.0 mL is indicated on the label.

BD Vacutainer® C&S Preservative Glass Urine Tubes have a 10.0 mL draw volume, 16 x 100 mm with a lyophilized maintenance formula and a gray stopper. A minimum fill line of 9.0 mL is indicated on the label.

The mean concentration of the preservative in the urine sample in BD Vacutainer® C&S Preservative Glass Urine Tubes is:

Boric Acid 6.70 mg/mL

Sodium Formate 3.35 mg/mL

All tubes have sterile interiors. Do not use tubes after their expiration date.

Intended Use of BD Vacutainer® C&S Preservative Urine Tubes

Bacteria quantification in urine is widely used as an aid in evaluating a patient for urinary tract infections. 1,2,3,4 Colony forming units of 100,000 microorganisms or greater per milliliter of urine are generally considered indicative of infection.4

Urine frequently supports the proliferation of bacteria, which may multiply at the same rate as in the nutrient broth.⁵ Therefore, a urine sample delayed in transit or left at room temperature for an extended period of time may give an erroneous result.6,3

As a means of preventing growth of the microorganisms from sources exogenous to the bladder, refrigeration or culturing within 2 hours of micturition is recommended.^{4,6,7} It is not always within the control of the laboratory to maintain the parameters necessary for accurate results. All BD Vacutainer® C&S Preservative Urine Tubes are intended for the collection and transport of urine samples for culture and sensitivity testing of bacteria

The tubes are filled with a lyophilized urine maintenance formula and evacuated to draw approximately 4.0 to 10.0 mL (depending on tube size) of urine. The lyophilized urine maintenance formula can maintain the bacterial population in the urine specimen for a period of up to 48 hours at room temperature at levels comparable to those urine specimens without additive, held under refrigeration for the same period of time.

Limitations of BD Vacutainer® C&S Preservative Urine Tubes

- 1. The quantity of specimen drawn varies with altitude, ambient temperature, barometric pressure, tube age, and filling technique.
- 2. Urine specimen must be drawn to the minimum fill line.

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- 3. It is not recommended to manually fill this tube. Removal of the stopper may compromise the sterility of the tube.
- 4. The maintenance formula will not inactivate antibiotics.
- 5. The microbial load in urine from a given patient may be influenced by the time of collection and fluid intake. Symptomatic patients may have counts below 105 microorganisms/mL if specimens are collected late in the day or if diuresis is occurring.3

BD Vacutainer® Urinalysis Urine Tubes Product Descriptions

BD Vacutainer $^{\circ}$ Urinalysis Conical Urine Tubes are 8.0 mL draw volume, 16 x 100 mm, with no additive and a yellow stopper.

BD Vacutainer® Urinalysis Urine Tubes are 10.0 mL draw volume,

 16×100 mm with no additive and a yellow stopper.

BD Vacutainer® Urinalysis Preservative Conical Urine Tubes are 8.0 mL draw volume, 16 x 100 mm with a urinalysis preservative and a yellow and cherry red stopper. A minimum fill line of 7.0 mL and maximum fill line of 9.0 mL is indicated on the label.

BD Vacutainer® Urinalysis Preservative Urine Tubes are 8.0 mL draw volume, 16 x 100 mm, with a urinalysis preservative and BD Hemogard™ Closure with yellow shield color. A minimum fill line of 7.0 mL and a maximum fill line of 9.0 mL is indicated on the label.

BD Vacutainer $^{\circ}$ Urinalysis Preservative Conical Urine Tubes and Urinalysis Preservative Urine Tubes are stable when stored between 4–25 $^{\circ}$ C.

The mean concentration of the preservative in the urine sample in BD Vacutainer® Urinalysis Preservative Conical Urine Tube and Urinalysis Preservative Urine Tube is:

Sodium Propionate 94%

Ethyl Paraben 5.6%

Chlorhexidine 0.4%

Intended Use of BD Vacutainer® Urinalysis Urine Tubes

BD Vacutainer® Urinalysis Urine Tubes, No Additive, are designed for automated and manual chemistry dipstick urinalysis and sediment analysis. BD Vacutainer® Urinalysis Conical Urine Tubes, No Additive, are designed for automated and manual chemistry dipstick urinalysis and to obtain sediment for examination. This tube is compatible with the KOVA® petter, providing standardization of microscopic sediment analyses.

BD Vacutainer® Urinalysis Preservative Conical Urine Tubes are designed for automated and manual chemistry dipstick urinalysis and to obtain sediment for examination. This tube is also compatible with the KOVA® petter, providing standardization of microscopic sediment analyses.

BD Vacutainer® Urinalysis Preservative Urine Tubes are designed for collection, storage and transport of urine specimens for automated chemistry dipstick and sediment examination.

The preservative allows for transport, testing and storage of the specimen up to 72 hours at room temperature. The urinalysis preservative is intended to inhibit the metabolism of or render non-viable the bacteria present in urine while maintaining their cellular integrity. Without the presence of a preservative, the bacteria continue to metabolize and reproduce, causing changes in the urine components measured in a routine urinalysis.

Limitations of BD Vacutainer® Urinalysis Urine Tubes

- 1. The quantity of specimen drawn varies with altitude, ambient temperature, barometric pressure, tube age, and filling technique.
- 2. Due to the instability of bilirubin and urobilinogen in urine when exposed to room temperature and light, testing should be performed as soon as possible or specimens should be stored protected from light.
- 3. The urinalysis tubes that do not contain preservative should be transported without delay to the laboratory for processing or properly refrigerated to prevent erroneous results due to bacterial growth and/or specimen deterioration.8
- 4. If the sample volume in the cup is insufficient to fill the urine tube, remove the stopper of the tube and pour the urine into the tube.
- 5. BD Vacutainer® Urinalysis Preservative Urine Tubes and BD Vacutainer® Urinalysis Preservative Conical Urine Tubes must be filled to the minimum fill line and not exceed the maximum fill line in order to maintain the proper additive to urine ratio.

Directions to manually fill BD Vacutainer® Urinalysis Preservative Conical Urine Tubes and Urinalysis Preservative Urine Tubes

- 1. Hold tube upright.
- 2. Remove stopper and place upside down on counter.
- 3. Pour urine into tube filling between the minimum and maximum fill lines on the tube label.
- 4. Replace the stopper securely and mix tube 8–10 times by inversion.
- 5. Label tube for transport to the laboratory.

Instructions For Removal of BD Hemogard™ Closure

- Grasp the tube with one hand, placing the thumb under the BD Hemogard™ Closure (for added stability, place arm on a solid surface). With the other hand, twist the BD Hemogard™ Closure while simultaneously pushing up with the thumb of the other hand ONLY UNTIL THE TUBE STOPPER IS LOOSENED.
- Move thumb away before lifting closure. DO NOT use thumb to push closure off the tube. If the urine specimen contains blood, an exposure hazard exists. To help prevent injury during removal, it is important that the thumb used to push upward on the closure be removed from contact with the tube as soon as the BD Hemogard™ Closure is loosened.
- 3. Lift closure off tube. In the unlikely event of the plastic shield separating from the rubber stopper, DO NOT REASSEMBLE CLOSURE. Carefully remove rubber stopper from tube.

Instructions For Reinsertion of BD Hemogard™ Closure

- Place closure over tube.
- Twist and push down until stopper is fully reseated. Complete reinsertion of stopper is necessary for the closure to remain securely on the tube during handling.

Equipment Required But Not Supplied for Urine Testing

- 1. Equipment for urinalysis and sediment examination.
- 2. Media and supplies for bacterial culture and identification.

NOTE: Practice Standard Precautions. Use gloves, gowns, eye protection, other personal protective equipment and engineering controls to protect from specimen splatter, leakage, and potential exposure to bloodborne pathogens or other infectious materials.

METHODS OF COLLECTION

BD Vacutainer® Urine Collection Cup

- 1. The healthcare professional obtains a cup for the patient and cautions patient not to remove the cap label to protect against needlestick from the "sharp" contained in the integrated transfer device. If a kit is used, the healthcare professional should remove the BD Vacutainer® Tube(s) and place them in a protected location before giving the cup to the patient for urine collection.
- If kits are provided to the patient, the patient should be directed to follow instructions on the bag for proper collection of a clean-voided, midstream urine specimen.
- 3. Patient is instructed to give the urine specimen to the healthcare professional immediately after collection.
- 4. To transfer the specimen into evacuated tube(s):
 - a. Place cup upright on clean, flat surface. Container may be tipped at an angle if specimen volume is limited.
 - b. Peel back label on cap to expose the integrated transfer device.
 - c. Place evacuated tube into cavity on cap, stopper down. Advance the tube over puncture point to pierce stopper. BD Vacutainer[©] C&S Preservative Urine Tubes should be filled first when collecting multiple tubes.
 - d. Hold tube in position until filled.
 - e. Remove tube from integrated transfer device.
 - f. For all BD Vacutainer $^{\circ}$ Preservative Urine Tubes, mix tubes 8–10 times by inversion.
 - g. Repeat steps c-f if another tube is to be filled.
 - h. Replace label over integrated transfer device cavity and reseal. Use caution to avoid contact with needle when replacing label.
- 5. Label tube(s) or cup for transport to laboratory.
- Treat the screw cap of the cup as a contaminated sharp and discard in biohazard container approved for sharps disposal as per your facility's recommended procedure.

BD Vacutainer® Urine Transfer Straw

- 1. If the urine specimen is collected into an alternate container, the patient gives the specimen to the healthcare professional.
- 2. To transfer the specimen into evacuated tube(s):
 - a. Place container on a clean, flat surface.
 - b. Place tip of transfer straw into urine specimen. Container may be tipped at an angle if volume of urine is limited.
 - c. Place evacuated tube into holder, stopper down. Advance the tube over puncture point to pierce stopper. BD Vacutainer® C&S Preservative Urine Tubes should be filled first when collecting multiple tubes.
 - d. Hold tube in position until filled.
 - e. Remove tube from holder.
 - For all BD Vacutainer® Preservative Urine Tubes, mix tubes 8–10 times by inversion.

- g. If another tube is to be filled, leave transfer straw in container and repeat steps c–f.
- Lift transfer straw from cup and allow specimen to drain. Discard transfer straw in a biohazard container approved for sharps disposal per your facility's recommended procedure.
- 4. Label the tube(s) for transport to the laboratory.

Centrifugation of Urine Tubes for Sediment Analysis

Recommended Relative Centrifugal Force (RCF) for centrifugation of BD Vacutainer® Urinalysis Urine Tubes with a urine sample is 600 g for 5 minutes in a swing head centrifuge. Always use appropriate centrifuge carriers or inserts for the specific tube size. Use of tubes with cracks, chips, excessive centrifugation speed or inappropriate carriers may cause tube breakage, with release of sample, droplets, or an aerosol into the centrifuge bowl. Release of these potentially hazardous materials can be avoided by using specially designed sealed containers in which tubes are held during centrifugation. Centrifuges should be balanced and properly calibrated. Revolutions per minute (rpm) can be converted to the relative centrifugal force by the following formula:



RCF = Relative Centrifugal Force

r = radial distance from center of centrifuge head to bottom of tube in centimeters. CAUTION: Do not exceed recommended centrifugation speed. BD Vacutainer® Urinalysis Urine Tubes will withstand up to 10,000 g in a balanced centrifuge

TRANSPORT OF URINE SPECIMEN

- For transport of cup to the laboratory, provide adequate warning using labeling and packaging to protect against inadvertent needlesticks caused by sharp located under label. Carefully replace label over integrated transfer device cavity. Treat the screw cap of the specimen container as a contaminated sharp.
- 2. Properly label tubes with patient name, i.d., collection date and time and any additional information required by your facility's policy.
- 3. Properly label and package any container used to transport specimen to alternate location in accordance with applicable local, state and federal requirements.

Analytic Equivalency

Evaluations of BD Vacutainer® Urine Tubes have been performed for an array of analytes over a variety of test methods. BD PAS Global Technical Services Department is available to answer questions regarding these tubes. Please contact them at 1.800.631.0174 (USA) to obtain references and any other information regarding the use of BD Vacutainer® Urine Tubes.

Whenever changing any manufacturer's collection tube type, size or storage condition for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if a change is appropriate.

PRECAUTIONS

- Caution should be used in handling the screw cap lid of the BD Vacutainer® Urine Collection Cup, which contains a needle under the label. Treat the screw cap of the cup as a contaminated sharp and discard in biohazard container approved for sharps disposal as per your facility's recommended procedure.
- 2. Caution should be used in handling the transfer straw that contains a needle and should be disposed of as a contaminated sharp after use.
- All biologic specimens and devices used to collect or store clinical specimens should be carefully handled and disposed of in accordance with the precautions recommended by the CDC, CLSI, and your facility's recommended procedures.
- If a urine specimen contains blood, all specimen collection devices must be classified as biohazardous for handling and disposal purposes.
- 5. Do not squeeze cup.

CAUTION

- Practice standard precautions. Use gloves, gowns, eye protection, other
 personal protective equipment and engineering controls to protect
 from specimen splatter, leakage, and potential exposure to bloodborne
 pathogens or other infectious materials.
- All biologic specimens and devices used to collect or store clinical specimens should be carefully handled and disposed of in accordance with the precautions recommended by the CDC, CLSI, and your facility's recommended procedures.
- 3. Discard all biologic samples in containers approved for their disposal per your facility's recommended procedures.
- Transferring a sample to a tube using a syringe and needle is not recommended. Additional manipulation of sharps such as hollow bore needles increases the potential for needlestick injuries.
- Transferring samples from syringe to an evacuated tube using non-sharps devices should be performed with caution for the reasons described below:
 - Depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample, causing splatter and potential exposure to infectious material.
 - Evacuated tubes are designed to draw the volume indicated.
 - Using a syringe for specimen transfer may also cause over or under filling of tubes resulting in the incorrect urine to additive ratio.
 Filling is complete when vacuum no longer continues to draw, though some tubes may partially fill due to plunger resistance when filled from a syringe. Consult your facility's policy and procedure regarding the use of these specimens for diagnostic evaluations.

REFERENCES

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TECHNICAL SERVICES

Technical Service and Support: In the United States contact BD at 1.800.631.0174 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

Change History

Revision	Date	Change Summary
(01)	02/2019	Initial release. Created as Web IFU. Content remains same as printed IFU VDP40100-08A. Added AU and NZ address. Updated Copyright Information.
(02)	02/2021	Added associated product catalog numbers. Contact information, trademark information, and Symbol Glossary updated. Updated Australian Sponsor address.

Symbol Glossary (US customers only: For symbol glossary refer to bd.com/symbols-glossary)				
EC REP	Authorized Representative in the European Community			
LOT	Batch code			
CE	CE marking			
REF	Catalogue number			
<u> </u>	Caution			
eifu.bd.com	Consult instructions for use			
Tel i	Contact regional telephone numbers to obtain printed instruction for use			
(2)	Do not re-use			
®	Do not use if package is damaged			
Ţ	Fragile, handle with care			
IVD	In vitro diagnostic medical device			
类	Keep away from sunlight			
	Manufacturer			
STERILE R	Sterilized using irradiation			
€\$	Recyclable			
	Temperature limit			
<u> </u>	This way up			
\Box	Use-by date			



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