BD Vacutainer®

Evacuated Blood Collection System

For *In Vitro* Diagnostic Use

REF 363047 REF 363048

INTENDED USE

BD Vacutainer® Tubes, Needles and Holders are used together as a system for the collection of venous blood. BD Vacutainer® Tubes are used to transport and process blood for testing serum, plasma or whole blood in the clinical laboratory.

PRODUCT DESCRIPTION

BD Vacutainer® Tubes are evacuated tubes with color-coded conventional stoppers or BD Hemogard™ Closures. BD Vacutainer® Plus Tubes are plastic tubes.
Most tube types contain additives in varying concentrations dependent upon the amount of vacuum and the required additive to blood ratio for the tube. See each shelf package or case label for specific additive quantity and approximate draw volume. Additive choice depends on the analytic test method. It is specified by the manufacturer of the test reagents and/or instrument on which the test is performed. Tube interiors are sterile. Tube stoppers are lubricated with silicone or glycerin (see individual shelf package or case label) to facilitate stopper insertion.

BD Vacutainer® Blood Collection Tube Reference*
ADDITIVE GROUP/ADDITIVE
Gel Separation Tubes
BD SST™ Tubes with Gel and Clot Activator
BD PST™ Tubes with Gel and Lithium Heparin[N 1]
Non-Additive Tubes
No Additive[2]
Serum Tubes with Additives
Plus Serum/CAT with Clot Activator
Whole Blood/Plasma Tubes
K_2EDTA or K_3EDTA**
K_2EDTA**
Citrate/CTAD (Coagulation)
Citrate (ESR)
Sodium Fluoride/Potassium Oxalate
Heparin[N 1]**
Acid Citrate Dextrose (ACD)
Trace Element Tubes***
K_2EDTA or with clot activator

*Closure color may vary for specific reorder numbers.
[1]HeparinN source is porcine. Devices labeled with a superscript letter 'N' indicate that the device contains heparin which has been certified to meet the requirements of USP Heparin Monograph October 1, 2009.

[2]May only be used as a discard tube or as a secondary specimen collection tube.

**BD Vacutainer® EDTA tubes and Lithium Heparin tubes are not recommended for use with Magellan Diagnostics LeadCare® assays employing the Anodic Stripping Voltammetry (ASV) methodology, or any other assay employing ASV methodology.

***For trace element testing including lead testing of venous blood, BD recommends using BD Vacutainer® Trace Element Testing Tube.

BD Vacutainer® Serum Tubes

BD Vacutainer® Plus Serum Tubes / CAT Tubes are coated with silicone and micronized silica particles to accelerate clotting. Particles in the white film on the interior surface activate clotting when tubes are mixed by inversions. A silicone coating on the walls of most serum tubes reduces adherence of red cells to tube walls. See Limitations of System, Precautions, Specimen Collection and Handling Sections.

BD Vacutainer® Tubes for Trace Element Tests

Tubes for trace element testing including lead testing are labeled specifically for this purpose on the shelf package and case label. Use only appropriately labeled tubes for these tests. The tubes for trace element testing have been tested by extraction of the stoppered tube for 4 hours, yielding results below these concentration limits:

BD Vacutainer® Trace Element Tubes Contamination Upper Limits					
Analyte	Glass µg/L	Plus µg/L	Analyte	Glass µg/L	Plus µg/L
Antimony	0.8		Lead	2.5	0.3
Arsenic	1.0	0.2	Magnesium	60	40
Cadmium	0.6	0.1	Manganese	1.5	1.5
Calcium	400	150	Mercury**	-	3.0
Chromium	0.9	0.5	Selenium	-	0.6
Copper	8.0	5.0	Zinc	40	40
Iron	60	25			

*BD Vacutainer® Trace Element Plus Tubes should not be used for antimony testing.
Water extraction analyzed by **Cold Vapor, all others Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) or Atomic Absorption Spectroscopy (AAS).

BD Vacutainer® SST™ Tubes

The interior of the tube wall is coated with micronized silica particles to accelerate clotting. A barrier polymer is present at the tube bottom. The density of this material causes it to move upward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from fibrin and cells. Serum may be aspirated directly from the collection tube, eliminating the need for transfer to another container. A silicone coating on the inner tube wall reduces adherence of red cells to tube walls. See Limitations of System, Precautions, Specimen Collection and Handling Sections.

BD Vacutainer® PST™ Tubes

The interior of the tube wall is coated with lithium heparin to inhibit clotting. Heparin activates antithrombins, thus blocking the coagulation cascade and producing a whole blood/plasma sample instead of clotted blood and serum. A barrier polymer is present at the tube bottom. The density of this material causes it to move upward during centrifugation to the plasma-cell interface, where it forms a barrier separating plasma from cells. Plasma may be aspirated directly from the collection tube, eliminating the need for transfer to another container. See Limitations of System, Precautions, Specimen Collection and Handling Sections.

BD Vacutainer® Tubes for Blood Banking

BD Vacutainer® Plus Serum Tubes, BD Vacutainer® Plus K_2EDTA Tubes, BD Vacutainer® Glass Serum Tubes, and BD Vacutainer® Glass K_3EDTA Tubes, may be used for routine immunohematology testing such as ABO grouping, Rh typing, antibody screening, red cell phenotyping and DAT testing, and blood donor screening for infectious disease such as Syphilis Ab, anti-HIV, anti-HTLV, anti-HCV, anti-HBc, and HBsAg. The performance characteristics of these tubes have not been established for immunohematology testing and infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

BD Vacutainer® SST™ Plus Tubes and BD Vacutainer® SST™ Glass Tubes may be used for routine blood donor screening and diagnostic testing of serum for infectious disease such as ToRCH, Syphilis Ab, anti-HIV, anti-HTLV, anti-HCV, anti-HBc, and HBsAg. The performance characteristics of these tubes have not been established for infectious disease testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

BD Vacutainer® CTAD Tubes

The CTAD tube is used for the collection and transport of specimens for hemostasis testing. The CTAD solution is a mixture of sodium citrate, theophylline, adenosine and dipyridamole. The purpose of the additive is to anticoagulate the specimen and to minimize *in vitro* platelet activation. See Precautions, Specimen Collection and Handling Sections.

BD Vacutainer® Plus Citrate Tubes

The tube component is comprised of two plastic tubes assembled together to maintain the draw volume and liquid additive. The tube contains buffered sodium citrate additive. All tube configurations are full draw and utilize BD Hemogard™ Closures. See Limitations of System, Precautions, Specimen Collection and Handling Sections. The product performance has been compared to the 4.5mL glass tube for routine coagulation assays on a variety of donor populations with clinically equivalent results obtained. Note: all studies were performed on donors with hematocrits between 25 and 55%.

The tube is designed to ensure appropriate fill level. Always allow the tube to fill until the blood ceases to flow. Information on correct tube fill level is provided below.

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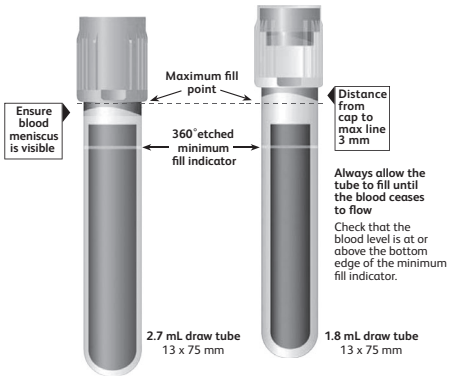
Minimum Fill Indicator:

The 360˚ etched fill indicator on the tube represents the minimum volume of blood required for appropriate analysis. Check that the blood level is at or above the bottom edge of the minimum fill indicator.

Maximum Fill Level Guidance:

For the 2.7 mL tube, if blood meniscus is not visible per the figure below, the tube is considered overfilled.

For the 1.8 mL tube, if blood meniscus is higher than level shown in the figure below, the tube is considered overfilled. The meniscus must be at least a distance of 3 mm from the bottom edge of the closure as shown in the figure below.



BD Vacutainer® Blood Collection Needles

BD Vacutainer® Blood Collection Needles are single-use, double-ended, medical grade stainless steel needles. They have a threaded hub that fits into the threads of all BD Vacutainer® Holders. The venipuncture end of the needle has a point specially designed to enter the skin easily during venipuncture. The needle is lubricated with silicone. The needles are available in 1 and 1-1/2 inch lengths in 20 and 21 gauge; blood collection sets are available in 3/4 inch lengths in 21, 23 and 25 gauge, BD Vacutainer® Passive Shielding Blood Collection Needles in 1 inch and 21 and 22 gauge and BD Vacutainer® Eclipse™ in 1-1/4 inch and 21 and 22 gauge. Needle size and lot number are printed on each individual needle assembly.

BD Vacutainer® Luer Adapter, BD Vacutainer® Luer-Lok™ Access Device, and BD Vacutainer® Blood Transfer Device are products designed with a luer fitting in place of the venipuncture end of the needle. The BD Vacutainer® Luer Adapter is a male slip-luer fitting opposing a multiple sample non-patient (NP) needle. It is designed to be used with a BD Vacutainer® Holder. The BD Vacutainer® Luer-Lok™ Access Device is a holder with an integrated multiple sample NP needle and threaded male luer fitting. The BD Vacutainer® Blood Transfer Device is a holder with an integrated multiple sample NP needle and locking female luer fitting.

Products have a latex free sleeve covering the NP needle that prevents leakage of blood into the holder during blood collection. The tubes slide into the holder and are pushed onto the NP needle, allowing the vacuum in the tube to draw blood to a predetermined level.

LIMITATIONS OF SYSTEM

The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Tubes with draw volume smaller than the apparent dimensions indicated (partial draw tubes), may fill more slowly than tubes of the same size with greater draw volume.

For tubes subjected to centrifugation to generate plasma or serum for testing, standard processing conditions do not necessarily completely sediment all cells, whether or not barrier gel is present. Cell–based metabolism, as well as natural degradation *ex vivo*, can continue to affect serum/plasma analyte concentrations/activities after centrifugation. Separated plasma samples in particular, will have a gradient of cells and platelets present after centrifugation. The presence of cells and platelets in the plasma may lead to increased variability and/or instability of certain analytes that are involved in cell/platelet–mediated metabolic processes and/or are present in higher concentrations in cells or platelets. Analytes that may be affected include aspartate aminotransferase, glucose, inorganic phosphorus, lactate dehydrogenase and potassium. The magnitude of such effects may vary depending on several factors, including whether the plasma is aliquoted or remains in the primary tube, sample agitation, and time. Analyte stability should be evaluated for the storage containers and conditions of each laboratory.

BD Vacutainer® PST™ Plus Tubes and BD Vacutainer® PST™ Glass Tubes are not recommended for the collection of samples for blood banking procedures. BD Vacutainer® SST™ Plus Tubes and BD Vacutainer® SST™ Glass Tubes are not recommended for immunohematology testing. BD Vacutainer® SST™ Plus Tubes can be used for certain TDM assays.

Do not use BD Vacutainer® Tubes containing lithium heparin for lithium measurement. For coagulation tests, if patient hematocrit is above 55%, the final citrate concentration in the specimen should be adjusted.

Venous blood gas samples collected with BD Vacutainer® Plastic Lithium Heparin tubes should not be used when testing carboxyhemoglobin (COHb) using the IL GEM 4000 instrument. A clinically significant positive bias with COHb results may occur.

PRECAUTIONS

1. Storage of glass tubes containing blood at or below 0ºC may result in tube breakage.
2. Do not remove conventional rubber stoppers by rolling with thumb. Remove stoppers with a twist and pull motion.
3. Do not use tubes or needles if foreign matter is present.
4. The paper label covering the connection of the needle shields will tear when the needle is opened. Do not use needle if label has been torn before venipuncture.
5. CTAD tubes must be protected from artificial and natural light during storage. Accumulated light exposure in excess of 12 hours can cause additive inactivation.
6. Separation of serum or plasma from the cells should take place within 2 hours of collection to prevent erroneous test results unless conclusive evidence indicates that longer contact times do not contribute to result error.
7. Do not use luer adapters for connection to indwelling catheters/ports; use a BD Vacutainer® Luer-Lok™ Access Device instead.
8. BD Vacutainer® EDTA tubes and Lithium Heparin tubes are not recommended for use with Magellan Diagnostics LeadCare® assays, employing the Anodic Stripping Voltammetry (ASV) methodology, or any other assay employing ASV methodology.

CAUTION

1. Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to bloodborne pathogens.
2. All glass has the potential for breakage. Examine all glass for potential damage in transit before use, and take precautionary measures during handling.
3. Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters, and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-inused needle protector, if the blood collection device provides one. BD does not recommend reshielding used needles. However, the policies and procedures of your facility may differ and must always be followed.
4. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
5. Transferring a sample collected using syringe and needle to a tube is not recommended. Additional manipulation of sharps, such as hollow bore needles, increases the potential for needlestick injury.
6. Transferring samples from syringe to an evacuated tube using a non-sharps device 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 blood exposure. • Using a syringe for blood transfer may also cause over or under filling of tubes, resulting in an incorrect blood-to-additive ratio and potentially incorrect analytic results. • Evacuated tubes are designed to draw the volume indicated. 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. The laboratory should be consulted regarding the use of these samples.
7. If blood is collected through an intravenous (I.V.) line, ensure that line has been cleared of I.V. solution before beginning to fill blood collection tubes. This is critical to avoid erroneous laboratory data from I.V. fluid contamination.
8. Overfilling or under filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
9. Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

STORAGE

Store tubes at 4-25ºC (39-77ºF), unless otherwise noted on the package label. All liquid preservatives and anticoagulants are clear and colorless, except CTAD which is yellow. Do not use if they are discolored or contain precipitates. Powdered additives such as heparin and thrombin are white; fluoride and fluoride/oxalate may be pale pink. Do not use if color has changed. EDTA spray coated additives may have a white to slightly yellow appearance; this does not affect the performance of the EDTA additive. Do not use tubes after their expiration date. Tubes expire on the last day of the month and year indicated.

SPECIMEN COLLECTION AND HANDLING

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING VENIPUNCTURE.

Required Equipment Not Provided for Specimen Collection

1. Practice Universal Precautions. Use gloves, eye protection, coats or gowns, and other appropriate apparel for protection from exposure to bloodborne pathogens or other potentially infectious materials.
2. Any BD Vacutainer® Needle Holders of the standard size may be used with 13 or 16 mm diameter tubes. A pediatric tube adapter should be used to modify the standard holder to fit the 10.25 mm diameter tubes.
3. Alcohol swab for cleansing site. If additional tubes requiring sterile collections, such as blood cultures, are filled from the same venipuncture, use tincture of iodine or suitable alternative for cleansing. Follow the laboratory policy for sterile sample collection for site preparation and tube handling instructions. Do not use alcohol based cleansing materials when samples are to be used for blood alcohol testing.

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4. Dry, clean disposable gauze.
5. Tourniquet.
6. Needle disposal container for used needle or needle/holder combination.

Required Equipment Not Provided for Specimen Processing

1. Disposable transfer pipets if direct sampling from the instrument is not used or if specimen is stored separately.
2. Centrifuge capable of generating the recommended RCF at the tube bottom. A horizontal centrifuge head is preferred for barrier quality with gel tubes and to obtain platelet poor plasma for coagulation studies.
3. Gloves and other personal protective equipment as necessary for protection from exposure to bloodborne pathogens.

Preparation for Specimen Collection

Be sure the following materials are readily accessible before performing venipuncture:

1. See Required Equipment Not Provided for Specimen Collection above.
2. All necessary tubes, identified for size, draw, and additive.
3. Labels for positive patient identification of samples.

Recommended Order of Draw

1. Tubes for sterile samples.
2. Tubes for coagulation studies (e.g., citrate).
3. BD SST™ and Serum Tubes.
4. Tubes with other additives (e.g., heparin, EDTA, fluoride).

When using a winged blood collection set for venipuncture and a coagulation (citrate) tube is the first specimen tube to be drawn, a discard tube should be used prior to the first specimen collection. The discard tube must be used to fill the blood collection set tubing's "dead space" with blood. The discard tube does not need to be filled completely. This step will ensure maintenance of the proper blood-additive-ratio of the specimen. The discard tube should be a non additive or coagulation tube. BD Vacutainer® SST™ Tubes and BD Vacutainer® Plus Serum Tubes / CAT Tubes contain particulate clot activators and are considered additive tubes. Therefore, Plus Serum Tubes are not to be used as discard tubes before drawing citrate tubes for coagulation studies.

Prevention of Backflow

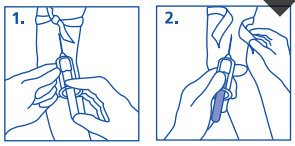
Since some evacuated blood collection tubes contain chemical additives, it is important to avoid possible backflow from the tube, with the possibility of adverse patient reactions. To guard against backflow, observe the following precautions:

1. Place patient's arm in a downward position.
2. Hold tube with the stopper uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube additives do not touch stopper or end of the needle during venipuncture.

Venipuncture Technique and Specimen Collection General Instructions

WEAR GLOVES DURING VENIPUNCTURE AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD.

1. Select tube or tubes appropriate for required specimen. For sterile collections, see the specific instructions noted in the collection device product circular.
2. Assemble needle in holder. Be sure needle is firmly seated to ensure needle does not unthread during use.
3. Gently tap tubes containing additives to dislodge any material that may be adhering to the stopper.
4. Place tube into holder. Note: Do not puncture stopper.
5. Select site for venipuncture.
6. Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.
7. Place patient's arm in a downward position.



8. Remove needle shield. Perform venipuncture WITH ARM DOWNWARD AND TUBE STOPPER UPPER-MOST.
9. Center tubes in holder when penetrating the stopper to prevent sidewall penetration and resultant premature vacuum loss. Push tube onto needle, puncturing stopper diaphragm.
10. REMOVE TOURNIQUET AS SOON AS BLOOD APPEARS IN TUBE. DO NOT ALLOW CONTENTS OF TUBE TO CONTACT THE STOPPER OR END OF THE NEEDLE DURING PROCEDURE.

Note: Blood may occasionally leak from the needle sleeve. Practice Universal Precautions to minimize exposure hazard. If no blood flows into tube or if blood ceases to flow before an adequate specimen is collected, the following steps are suggested to complete satisfactory collection:

   a. Push tube forward until tube stopper has been penetrated. If necessary, hold in place to ensure complete vacuum draw.
   b. Confirm correct position of needle cannula in vein.
   c. REMOVE TUBE AND PLACE NEW TUBE INTO THE HOLDER.
   d. If second tube does not draw, remove needle and discard. Repeat procedure from Step 1.
11. When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
12. Place succeeding tubes in holder, puncturing diaphragm to begin flow. See Recommended Order of Draw.
13. While each successive tube is filling, turn the filled tube upside-down and return it to upright position. This is one complete inversion.

For proper additive performance, invert BD SST™ Tubes or Plus Serum Tubes 5 times. Invert BD CAT Tubes 5-6 times. Invert Citrate or CTAD tubes 3-4 times. Invert all other filled additive tubes 8-10 times. Do not shake. Vigorous mixing may cause foaming or hemolysis. Insufficient mixing or delayed mixing in serum tubes may result in delayed clotting and incorrect test results. In tubes with anticoagulants, inadequate mixing may result in platelet clumping, clotting and/or incorrect test results.

14. As soon as blood stops flowing in the last tube, remove tube from holder, remove needle from vein, applying pressure to puncture site with dry sterile swab until bleeding stops.
15. Once clotting has occurred, apply bandage if desired.
16. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
17. Dispose of needle and holder per your facility's policy and guidelines.

Clotting Instructions

Allow blood to clot thoroughly before centrifugation. The following table gives the recommended minimum clotting times for specific tube types or additives.

Minimum Clotting Time Recommendations	
PRODUCT	TIME (min)
Serum / CAT Tubes	60
BD SST™ Tubes	30

Recommended times are based upon an intact clotting process. Patients with abnormal clotting due to disease, or those receiving anticoagulant therapy require more time for complete clot formation.

Centrifugation

Caution: Do not centrifuge glass tubes at forces above 2200 RCF in a horizontal head (swinging bucket) centrifuge as breakage may occur. Glass tubes may break if centrifuged above 1300 RCF in fixed angle centrifuge heads. BD Vacutainer® Plus Tubes will withstand up to 10,000 RCF in a balanced centrifuge. Always use appropriate carriers or inserts. Use of tubes with cracks or chips or excessive centrifugation speed may cause tube breakage, with release of sample, droplets, and 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. Centrifuge carriers and inserts should be of the size specific to the tubes used. Use of carriers too large or too small for the tube may result in breakage.

RCF is related to centrifuge speed setting (rpm) using the following equation:

$$rpm = \sqrt{\frac{RCF \times 10^5}{1.12 \times r}}$$

where "r", expressed in cm, is the radial distance from the center of the centrifuge head to the bottom of the tube.

The following table gives recommended centrifuge RCF and time:

Centrifugation RCF and Time*		
PRODUCT	RCF (g)	TIME (min)
BD SST™ and BD PST™ Tubes (glass)	1000 – 1300	10
BD SST™ Plus and BD PST™ Plus Tubes - 13mm	1100 – 1300	10
BD SST™ Plus and BD PST™ Plus Tubes - 16mm	1000 – 1300	10
BD SST™ Transport Tubes	1100 – 1300	15
All Non-gel Tubes	≤ 1300	10
Citrate Plus Tubes	2000 – 2500**	10 – 15**

15 minutes for all gel tubes in a fixed angle centrifuge

RCF = Relative Centrifuge Force, g's

*Use of alternate centrifugation conditions (e.g., higher RCF and shorter spin time) may also provide acceptable performance; this should be evaluated and validated by the laboratory.

**Citrate tubes should be centrifuged at a speed and time to consistently produce platelet-poor plasma (platelet count <10,000/µL) per CLSI Guidelines.

Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in separation of the BD Hemogard™ Closures from the tube or extension of the tube above the carrier. Tubes extending above the carrier could catch on centrifuge head, resulting in breakage. Balance tubes to minimize the chance of glass breakage. Match tubes to tubes of the same fill level, glass tubes to glass, tubes with BD Hemogard™ Closures to others with the Closure, gel tubes to gel tubes, BD Vacutainer® Plus Tubes with Plus Tubes, and tube size to tube size.

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Change #: 500000247445
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Always allow centrifuge to come to a complete stop before attempting to remove tubes. When centrifuge head has stopped, open the lid and examine for possible broken tubes. If breakage is indicated, use mechanical device such as forceps or hemostat to remove tubes. Caution: Do not remove broken tubes by hand.

See centrifuge instruction manual for disinfection instructions.

Barrier Information

The flow properties of the barrier material are temperature-related. Flow may be impeded if chilled before or during centrifugation. To optimize flow and prevent heating during centrifugation, set refrigerated centrifuges to 25°C (77°F).

Tubes should not be re-centrifuged once barrier has formed. Barriers are more stable when tubes are spun in centrifuges with horizontal (swinging bucket) heads than those with fixed angle heads.

Separated serum or plasma is ready for use. The tubes may be placed directly on the instrument carrier or serum/plasma may be pipetted into an analyzer cup. Some instruments can sample directly from a separator tube with the stopper in place. Follow the instrument manufacturer's instructions.

ANALYTIC EQUIVALENCY

Evaluations of BD Vacutainer® Tubes have been performed for an array of analytes over a variety of test methods and time periods. BD Life Sciences - Integrated Diagnostic Solutions is available to answer questions regarding these studies. Please contact them to obtain references and technical reports on these evaluations and any other information regarding the use of BD Vacutainer® Tubes with your instrument/reagent system.

TECHNICAL SERVICES

In the U.S. please contact:

BD Life Sciences - Integrated Diagnostic Solutions
1 Becton Drive
Franklin Lakes, NJ 07417

1.800.631.0174 **eifu.bd.com**

Outside the U.S. please contact your local BD representative.

Whenever changing any manufacturer's blood collection tube type, size, handling, processing 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.

REFERENCES

CLSI Document H1-A6. Tubes and Additives for Venous and Capillary Blood Specimen Collection; approved standard, 6th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

CLSI Document H3-A6. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; approved standard, 6th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.

Landt M, Smith CH and Hortin GL. Evaluation of evacuated blood-collection tubes: Effects of three types of polymeric separators on therapeutic drug-monitoring specimens. Clin Chem 1993; 39:1712-1717.

Dasgupta A, Dean R, Saldana S, Kinnaman G and McLawhon RW. Absorption of therapeutic drugs by barrier gels in serum separator blood collection tubes. Am J Clin Path 1994; 101:456-461.

Yawn BP, Loge C and Dale J. Prothombin time, one tube or two? Am J Clin Path 1996; 105:794-97.

Gottfried, EL and Adachi, MM. Prothrombin time (PT) and activated partial prothrombin time (APTT) can be performed on the first tube. Am J Clin Path 1997; 107:681-683.

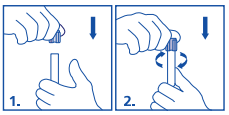
CLSI Document H21-A5. Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; approved guideline, 5th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2008.

CLSI Document H18-A4. Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; approved guideline, 4th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

Instructions for Removal of BD Hemogard™ Closure

1. Grasp the BD Vacutainer® Tube with one hand, placing the thumb under the BD Hemogard™ Closure. (For added stability, place arm on 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.
2. Move thumb away before lifting closure. DO NOT use thumb to push closure off tube. **Caution: Any glass tube has the potential to crack or break. If the tube contains blood, an exposure hazard exists.** To help prevent injury during closure 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



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

Change History

Revision	Date	Change Summary
(01)	2021-08	Initial Release

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SYMBOLS GLOSSARY [L006715(05) 2021-04]

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
EC REP	Authorized representative in the European Community
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE	Sterile
STERILE A	Sterilized using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat
	Do not resterilize
NON STERILE	Non-sterile
	Do not use if package is damaged
STERILE	Sterile fluid path
STERILE EO	Sterile fluid path (ethylene oxide)
STERILE R	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
	Humidity limitation
	Biological risks
	Do not re-use
	Consult instructions for use For electronic instructions for use, the url accompanies the symbol.
	Caution
LATEX	Contains or presence of natural rubber latex
IVD	*In vitro* diagnostic medical device
CONTROL -	Negative control
CONTROL +	Positive control
Σ	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic
#	Patient number
	This way up
	Do not stack
	Single sterile barrier system
PHT DEHP BBP	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)

Symbol	Meaning
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
CE	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
Rx Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
CC	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
	Collection date
	Keep away from light
H_2	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
MD	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
	Meets FCC requirements per 21 CFR Part 15
c UL us	UL product certification for US and Canada
UDI	Unique device identifier

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