D.10 Product Circular

The product circular, which is a common product circular for blood collection tubes, will be updated to reflect new claims associated with the device.

The existing product circular associated with the predicate devices currently state the following with regard to serum tubes:

Predicate Device Text

> **BD Vacutainer® Serum Tubes**
> BD Vacutainer® Plus Plastic Serum 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 5 times by inversion. See Limitations of System, Precautions, Specimen Collection and Handling Sections.
>
> A silicone coating on the walls of most serum tubes reduces adherence of red cells to tube walls.

The common product circular, associated with the principal BD Vacutainer® Plus Plastic Serum Tube, will be changed to state the following:

Principal Device Text

> **BD Vacutainer ® Serum Tubes**
>
> BD Vacutainer® Plus Plastic Serum 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 5 times by inversion. See Limitations of System, Precautions, Specimen Collection and Handling Sections.
>
> BD Vacutainer® Plus Plastic Serum Tubes and BD Vacutainer® Brand Glass Serum Tubes can be used for immunohematology testing including but not limited to ABO grouping, Rh typing, antibody screening, red cell phenotyping and DAT testing, which requires red blood cells or serum.
>
> A silicone coating on the walls of most serum tubes reduces adherence of red cells to tube walls.

An example of where this text may appear on the existing product circular is shown later in this section and is denoted as "**Updated Text**".

BD Evacuated Blood Collection System

For In Vitro Diagnostic Use.

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 (see table below) conventional stoppers or BD Hemogard™ Closures. BD Vacutainer® Plus Plastic Tubes are plastic tubes. Both 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 glycerine (see individual shelf package or case label) to facilitate stopper insertion.

BD Vacutainer® Tube Closure Color Code Cross Reference

ADDITIVE GROUP/ADDITIVE	CONVENTIONAL CLOSURE	BD HEMOGARD™ CLOSURE
Gel Separation Tubes		
BD SST™ Tubes with Gel and Clot Activator	Red/Grey	Gold
BD PST™ Tubes with Gel and Lithium Heparin[1]	Green/Grey	Light Green
Non-additive Tubes		
Silicone Coated	Red	Red
Uncoated	Red	Pink
Serum Tubes with Additives		
Thrombin[2]	Yellow/Grey	Orange
Plus Plastic Serum with clot activator	Red	Red
Thrombin[2], Soybean Trypsin Inhibitor	Light Blue	Light Blue
Whole Blood/Plasma Tubes		
K_2EDTA or K_3EDTA	Lavender	Lavender / Pink
Citrate/CTAD (Coagulation)	Light Blue	Light Blue or Clear
Citrate (ESR)	Black	Black
Sodium Fluoride/Sodium EDTA (Glucose)	Grey	Grey
Sodium Fluoride/Potassium Oxalate (Glucose)	Grey	Grey
Heparin[1]	Green	Green
Acid Citrate Dextrose (ACD)	Yellow	N/A
Sodium Polyanethol Sulfonate (SPS)	Yellow	N/A
Trace Element Tubes		
Silicone Coated, Heparin[1] or EDTA	N/A	Royal Blue
Lead Tubes		
Heparin[1]	N/A	Tan
K_2EDTA	N/A	Tan

[1]Heparin source is porcine. [2]Thrombin source is bovine.

Updated Text

BD Vacutainer® Tubes for Lead and Trace Element Tests

Tubes for lead testing and other trace elements are labeled specifically for these purposes on the shelf package and case label. Use only appropriately labeled tubes for these tests. BD Vacutainer® glass Tubes with a tan closure for lead testing contain sodium heparin and have been tested to a maximum of 10 µg/L of lead. BD Vacutainer® Plus Plastic Tubes for lead testing have K_2EDTA anticoagulant. The Plus Plastic Tubes have a maximum of 2.5 µg/L of lead and are also suitable for routine hematology testing. The tubes for trace elements have been tested by water or acid extraction of the stoppered tube for 4 hours. Atomic absorption spectroscopy testing yielded results below these concentration limits:

BD Vacutainer® Trace Element Tubes Contamination Upper Limits

ANALYTE	µg/L	ANALYTE	µg/L	ANALYTE	µg/L	ANALYTE	µg/L
Antimony	0.8	Calcium	400.*	Iron	60	Manganese	1.5
Arsenic	1.0	Chromium	0.9	Lead	2.5	Zinc	40*
Cadmium	0.6	Copper	8.0	Magnesium	60*		

*Flame technique, all others flameless

BD Vacutainer® SST™ Tubes and Transport 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. BD SST™ Transport Tubes contain the same clot activator as BD SST™ Tubes with approximately twice the quantity of barrier. This additional material produces a larger barrier between the serum and cells that is more stable for shipping from a phlebotomy site to a testing site. 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 plus 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. Supernatant plasma may be aspirated directly from the collection tube, eliminating the need for manual transfer to another container. Plasma obtained in BD PST™ Tubes should be tested or removed from the tube within 2 hours of collection according to the NCCLS Guidelines. See Limitations of System, Precautions, Specimen Collection and Handling Sections.

BD Vacutainer® Tubes for Immunohematology

The BD Vacutainer® Plus Plastic Tube K_2EDTA as well as the BD Vacutainer® Glass Serum and K_3EDTA Tubes may be used for routine immunohematology testing i.e. red cell grouping, Rh typing and antibody screens. Tubes must be filled to capacity (until vacuum is exhausted). Additive tubes (K_2 or K_3) must be inverted 8 to 10 times to assure complete mixing with blood, as erroneous results may occur. See Limitations of System, Precautions, Specimen Collection and Handling Sections.

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 Limitations of System, Precautions, Specimen Collection and Handling Sections.

BD Vacutainer® Plus Plastic Citrate Tubes

The tube component is comprised of two plastic tubes assembled together to maintain the draw volume and liquid additive. The tube contains 0.109M (3.2%) 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%.

BD Vacutainer® Blood Collection Needles

BD Vacutainer® Blood Collection Needles are single-use, double-ended, stainless steel needles. They have a threaded hub that fits into the threads of all BD Vacutainer® Needle 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.

BD Vacutainer® Multiple Sample Needles have a rubber sleeve covering the non-patient end of the needle that prevents leakage of blood into the holder during venipuncture. This Product Contains Dry Natural Rubber.

The tubes slide into the holder and are pushed onto the back end of the needle, allowing the vacuum in the tube to draw blood to a predetermined level. The needles are available in 1 and 1-1/2 inch lengths, in 20, 21, and 22 gauge. Needle size and Lot number are printed on each individual needle assembly.

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 those 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. Accordingly, cell-based metabolism, as well as natural degradation *ex vivo* affects serum/plasma analyte concentrations/activities beyond acellular changes. It is recommended that testing for glucose, uric acid, and lactate dehydrogenase (LD) be performed as soon after collection and separation as possible. Due to natural degradation, delay in separation of the serum or plasma from the cellular mass or in testing after separation will result in erroneous results for those analytes.

Prior to using CTAD tubes to collect specimens from warfarin patients for PT determinations with citrate sensitive reagents, please contact the BD Technical Services Department at 1-800-631-0174.

BD Vacutainer® SST™ Tubes, PST™ Tubes, and Plus Plastic Serum Tubes are not recommended for collection of samples for blood banking procedures. Glass EDTA and glass Serum Tubes are acceptable for blood banking procedures. BD Vacutainer® SST™ glass Tubes, PST™ Tubes and tubes with stoppers containing TBEP are not recommended for collection of samples for therapeutic drug monitoring (TDM) assays. BD Vacutainer® SST™ Plus Plastic tubes can be used for certain TDM assays. Please contact BD Technical Services Department at 1-800-631-0174 for details.

Do not use BD Vacutainer® PST™ Tubes for lithium measurement.

For coagulation tests, if patient hematocrit is above 55%, the final citrate concentration in the specimen should be adjusted.

PRECAUTIONS

1. Storage of glass tubes containing blood at or below 0°C 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. BD Vacutainer® Plus Plastic Serum Tubes with clot activator are not to be used as a discard tube for coagulation studies.
7. Separation of serum or plasma from the cells should take place within 2 hours of collection to prevent erroneous test results.

CAUTION:

1. Practice Standard 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-in used 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 underfilling 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 underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.

STORAGE

Store tubes at 4-25°C (39-77°F), 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 and freeze-dried additives such as EDTA, heparin, and thrombin are white; fluoride and fluoride/oxalate may be pale pink. Do not use if color has changed. Do not use tubes after their expiration date.

SPECIMEN COLLECTION and HANDLING

READ THIS ENTIRE CIRCULAR BEFORE PERFORMING VENIPUNCTURE.

Required Equipment Not Provided for Specimen Collection

1. Practice Standard 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. Use the small (pediatric) needle holder with 10.25 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.
4. Dry sterile 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 BD SST™ and PST™ 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 without additives
3. Tubes for coagulation studies (e.g., citrate)
4. Tubes with other additives (e.g., heparin, EDTA clot activator)

BD SST™ Tubes and BD Vacutainer® Plus Plastic Serum Tubes contain particulate clot activators and are considered additive tubes. Therefore Plus Plastic Serum Tubes are not to be used as discard tubes before drawing citrate tubes for coagulation studies. A glass discard tube must be used if only citrate tubes are drawn with a Blood Collection Set for venipuncture.

Prevention of Backflow

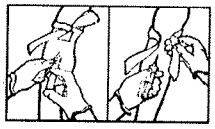
Since some evacuated blood collection tubes contain chemical additives, it is important to avoid possible backflow from the tube, with the possibility of adverse patient reactions. To guard against backflow, observe the following precautions:

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. If drawing sterile specimen, use a sterile holder.
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 Standard 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. If the BD Vacutainer® Multiple Sample Needle is used, remove tube and place new tube onto 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, and Plus Plastic Serum Tubes 5 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 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. Any needle holder that becomes contaminated with blood is considered hazardous and should be decontaminated with bleach or disposed of.
17. Dispose of the used needle using an appropriate disposal device. DO NOT RESHIELD. Reshielding of needles increases the risk of needlestick injury and blood exposure.

Clotting Instructions

Allow blood to clot thoroughly before centrifugation. The following table gives the recommended minimum clotting times for specific tube types or additives: BD SST™ Tubes, and Plus Plastic Serum Tubes should be inverted five times.

Minimum Clotting Time Recommendations	
PRODUCT	TIME (min)
Serum Tubes (Red or Pink Closures)	60
BD SST™ Tubes	30
Thrombin Tubes	5

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. Separation of serum or plasma from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines. See Limitations of System, Precautions, Specimen Collection and Handling Sections.

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 Plastic 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 either of the following equations:

$$rpm = \sqrt{\frac{RCF \times 10^5}{1.12 \times r}} \quad \text{or approximately} \quad rpm = \frac{10{,}000}{\sqrt{r}}$$

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 PST™ Tubes (glass)	1000 - 1300	10
BD SST™ Plus Plastic and PST™ Plus Plastic Tubes – 13mm	1100 - 1300	10
BD SST™ Plus Plastic and PST™ Plus Plastic Tubes – 16mm	1000 - 1300	10
BD SST™ Transport Tubes	1100 - 1300	15
All non-gel tubes	≤1300	10
Citrate Tubes*	1500	15

RCF = Relative Centrifugal Force, g's

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

Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in separation of the BD Hemogard™ Closure 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™ Closure to others with the Closure, gel tubes to gel tubes, BD Vacutainer® Plus Plastic Tubes with Plus Tubes, and tube size to tube size.

The following table relates radius of centrifuge arm to minimum required speed, in order to obtain the appropriate g-force.

Centrifuge Radius / Speed							
RADIUS (cm)	SPEED (rpm)	RADIUS (cm)	SPEED (rpm)	RADIUS (cm)	SPEED (rpm)	RADIUS (cm)	SPEED (rpm)
7	3750	12	2900	17	2400	22	2100
8	3500	13	2750	18	2350	23	2060
9	3300	14	2650	19	2280	24	2030
10	3150	15	2550	20	2200	25	2000
11	3000	16	2500	21	2160	26	1950

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). Gel separation tubes should be centrifuged no later than 2 hours after collection.

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. Plasma and serum from non-gel tubes should be removed from the cell layer within 2 hours of sample collection. Note: Some push-down filters may not be compatible with plastic tubes due to the tapered inner diameter of the tube.

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. The BD Technical Services Department 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.

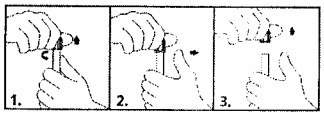
BD Technical Services may be reached at 800-631-0174. You may write to BD Diagnostics for information at:
BD Technical Services
BD, Franklin Lakes, NJ 07417
www.bd.com

Whenever changing any manufacturer's blood 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 changes are appropriate.

REFERENCES

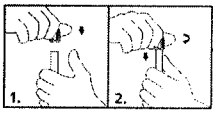
NCCLS Document H1-A4. Evacuated Tubes and Additives for Blood Specimen Collection; approved standard, 4th ed. Wayne, PA: National Committee for Clinical Laboratory Standards; 1996.
NCCLS Document H3-A4. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; approved standard, 4th ed. Wayne, PA. National Committee for Clinical Laboratory Standards; 1998.
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.
NCCLS Document H21-A3. Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays; approved guideline, 3rd ed. Wayne, PA: National Committee for Clinical Laboratory Standards; 1998.

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.

Symbol Key:

Do Not Reuse	STERILE EO Method of Sterilization Using Ethylene Oxide	EC REP Authorized Representative	Biological Risk
Use By	STERILE R Method of Sterilization Using Irradiation	For IVD Performance Evaluation Only	Fragile, Handle With Care
LOT Batch Code	STERILE Method of Sterilization Using Steam or Dry Heat	IVD In Vitro Diagnostic Medical Device	Keep Away from Sunlight
Date of Manufacture	REF Catalog Number	Temperature Limitation	This End Up
STERILE Sterile	Caution, Consult Accompanying Documents	Consult Instructions For Use	Recyclable
	Manufacturer		

EC REP BD, Belliver Industrial Estate Plymouth, PL6 7BP U.K. BD, Franklin Lakes, NJ 07417 USA

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