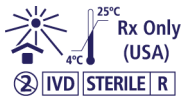
BD Vacutainer®

Barricor™ Lithium Heparin[N] Plasma Blood Collection Tubes

For *In Vitro* Diagnostic Use

EN



INTENDED USE

BD Vacutainer® Barricor™ Lithium Heparin[N] Plasma Blood Collection Tubes (BD Barricor™ Tubes) are used to collect, separate, process, transport, and store venous blood samples for use in chemistry determinations, therapeutic drug monitoring, and zinc testing in plasma for *in vitro* diagnostic use. It is used in settings where a venous blood sample is collected by a trained healthcare worker.

PRODUCT DESCRIPTION

BD Barricor™ Tubes are sterile (interior), single-use, evacuated blood collection tubes for collecting, separating, processing, transporting, and storing plasma in a closed tube. These products are comprised of a plastic tube containing a mechanical separator (in place of gel), a low-zinc stopper and a plastic BD Hemogard™ color-coded Lime Green safety-engineered shield. The interior of the BD Barricor™ Tube is spray coated with a lithium heparin anticoagulant. Tubes contain less than 50 µg/L of zinc to facilitate zinc testing. These tubes are available in 13x75mm and 13x100mm configurations with various nominal draw volumes ranging from 3.0mL to 5.5mL. Tube stopper and mechanical separator are lubricated with silicone based surfactant to facilitate product assembly.

LIMITATIONS OF SYSTEM

The BD Barricor™ Tube is not designed for use with fixed angle centrifuges. If spun in a fixed angle centrifuge, a barrier between the plasma and the cellular material will not be formed.

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 for testing, standard processing conditions do not necessarily completely sediment all cells, whether or not the mechanical separator barrier is present. Cell-based metabolism, as well as natural degradation ex vivo, can continue to affect plasma analyte concentrations/activities after centrifugation. Analyte stability should be evaluated for the storage containers and conditions of each laboratory.

BD Barricor™ Tubes are not recommended for the collection of samples for blood banking or immunohematology test procedures. Do not use BD Vacutainer® Tubes containing lithium heparin for lithium measurement.

The BD Barricor™ Tube is not designed for use with open blood collection systems (manual filling of tube with the BD Hemogard™ removed) due to the increased risk of exposure to blood borne pathogens. Blood should be collected directly into the tube or transfer devices should be used if blood is collected in a syringe.

CAUTIONS AND WARNINGS

Cautions

1. Examine tubes prior to use. Do not use tubes if foreign matter is present.
2. Since the BD Barricor™ Tube contains chemical additives, it is important to avoid possible backflow from the tube during blood collection. To guard against backflow, observe the following precautions:
   a. Place patient's arm in a downward position.
   b. Hold tube with the stopper uppermost
   c. Release tourniquet as soon as blood appears in tube.
3. Do not shake. Vigorous mixing may cause foaming or hemolysis.
4. If tubes are not mixed 8 times immediately after collection, clotting of plasma may occur. This may also result in fibrin formation.
5. Separation of plasma from cells by centrifugation should take place within 2 hours of collection to prevent erroneous test results. Tubes should not be re-centrifuged once mechanical barrier is in place. Re-centrifugation will cause mixing of the plasma above and below the barrier which may impact performance. Handling conditions can be evaluated and validated by the laboratory.
6. Remove BD Hemogard™ closures with a twist and pull motion. Removal by rolling with the thumb is not recommended.
7. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
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.

Warnings

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 blood-borne pathogens.
2. 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 re-shielding used needles. However, the policies and procedures of your facility may differ and must always be followed.
3. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
4. Transferring a sample collected using a syringe and needle to a tube is not recommended. Additional manipulation of sharps, such as hollow bore needles, increases the potential for needle-stick injury.
5. Transferring samples from syringe to an evacuated tube using a non-sharps device should be performed with caution for the following reasons:
   a. Depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing a potential blood exposure.
   b. 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.
   c. Evacuated tubes are designed to draw the volume indicated.
   d. 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.
6. 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.
7. Discard blood collection tubes in biohazard containers approved for their disposal.

STORAGE

Store BD Barricor™ Tubes at 4°C - 25°C (39°F - 77°F). 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 Universal Precautions. Use gloves, eye protection, coats or gowns, and other appropriate apparel for protection from exposure to blood borne pathogens or other potentially infectious materials.
2. Any BD Vacutainer® Needle Holders of the standard size may be used with 13mm 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, 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 swing bucket centrifuge is required for barrier formation in the BD Barricor™ Tubes.
3. Gloves and other personal protective equipment as necessary for protection from exposure to blood borne 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. Serum tubes with or without gel.
4. BD Barricor™ Tubes and tubes with other heparin additives.
5. Tubes with other additives (eg. EDTA, fluoride).

Note: 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.

Prevention of Backflow

Since BD Barricor™ Tubes contain chemical additives, it is important to avoid possible backflow from the tube.

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. Select site for venipuncture.

4. Apply tourniquet. Prepare venipuncture site with an appropriate antiseptic. DO NOT PALPATE VENIPUNCTURE AREA AFTER CLEANSING.
5. Place patient's arm in a downward position.
6. Remove needle shield. Perform venipuncture WITH ARM DOWNWARD AND TUBE STOPPER UPPER-MOST.

7. Center tube in holder when penetrating the stopper to prevent sidewall penetration and resultant premature vacuum loss. Push tube onto needle, puncturing stopper diaphragm.

8. 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. 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.

9. When first tube has filled to its stated volume and blood flow ceases, remove it from holder.
10. Place succeeding tubes in holder, puncturing diaphragm to begin flow.
11. While each successive tube is filling, turn the filled tube upside-down and return it to upright position. This action is defined as one complete inversion. For proper additive performance, immediately and gently invert the BD Barricor™ Tube 8 times. Do not shake. Vigorous mixing may cause foaming or hemolysis. Insufficient mixing or delayed mixing in plasma tubes may result in clotting and potentially incorrect test results.
12. 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 clean gauze until bleeding stops.
13. Once clotting has occurred, apply bandage if desired.
14. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.
15. Dispose of needle and holder per your facility's policy and guidelines.
16. Centrifuge tubes at 4000 RCF (g) for 3 minutes in a swing bucket centrifuge within 2 hours of collection. Tubes may also be centrifuged at alternate conditions as validated by your laboratory. See Centrifugation section for alternate centrifugation condition guidelines.

CENTRIFUGATION

Caution: BD Barricor™ Tubes will withstand up to 5,000 RCF (g) (Relative Centrifuge Force or g's) 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.

BD Barricor™ tubes are only compatible with swing bucket centrifuges. If spun in a fixed angle centrifuge, a barrier between the plasma and the cellular material will not be formed. BD has not validated performance when the tube is centrifuged in a fixed angle centrifuge.

Optimal Recommended centrifugation condition is 4000 RCF (g) for 3 minutes.

Alternate Centrifugation Conditions between 1800 RCF (g) – 5000 RCF (g) can be used with the appropriate centrifugation time (Table 1), tube configuration (Graph 1) and centrifuge rotor radius (Graph 1). Example centrifugation conditions from Graph 1 have been provided in Table 2. Refer to both Table 1 and Graph 1 to determine the minimum required centrifugation conditions.

Table 1. Alternate Centrifugation Conditions

RCF (g) Range	Minimum Centrifugation Time	Notes
1800 to 2499	10 Minutes	Refer to Graph 1
2500 to 2999	7 Minutes	
3000 to 3999	5 Minutes	-
4000 to 5000	3 Minutes	Optimal centrifugation condition

Graph 1. Minimum RCF (g) by Centrifuge Rotor Radius and Tube Configuration

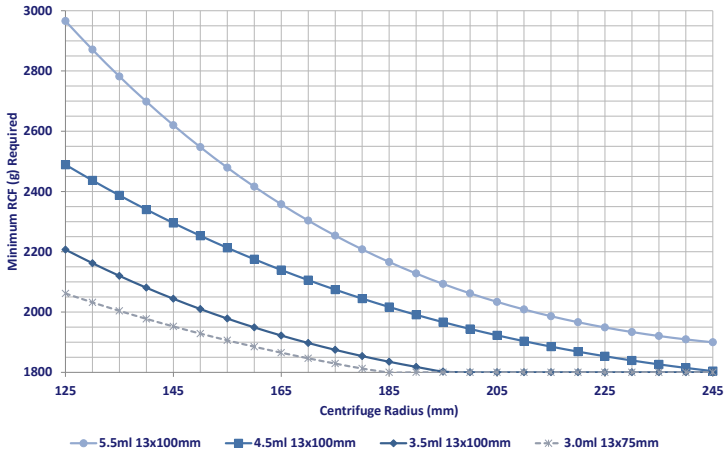


Table 2. Example Minimum RCF (g) values by Centrifuge Rotor Radius and Tube Configuration

Tube Configuration	Small Centrifuge	Medium Centrifuge	Large Centrifuge
	Radius = 125mm	Radius = 145mm	Radius = 185mm
5.5ml - 13x100mm	3000g	2650g	2200g
4.5ml - 13x100mm	2500g	2300g	2050g
3.5ml - 13x100mm	2200g	2050g	1850g
3.0ml - 13x75mm	2100g	1950g	1800g

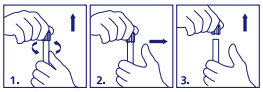
Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in separation of the BD Hemogard™ closures from the tube or extension of the tube above the carrier. Tubes extending above the carrier could catch on centrifuge head, resulting in breakage. Match tubes to similar tubes (tube material, closure type, fill volume, tube type, tube size).

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.

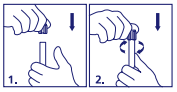
See centrifuge instruction manual for disinfection instructions.

INSTRUCTIONS FOR REMOVAL OF BD HEMOGARD™ CLOSURE



1. Grasp the BD Barricor™ 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 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 RE-ASSEMBLE 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.

ANALYTICAL EQUIVALENCY

Evaluations of BD Barricor™ Tubes have been performed for selected analytes on certain instrument platforms. See Table 3. The BD Technical Services Department is available to provide information regarding these studies.

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 changes are appropriate.

ANALYTE STABILITY

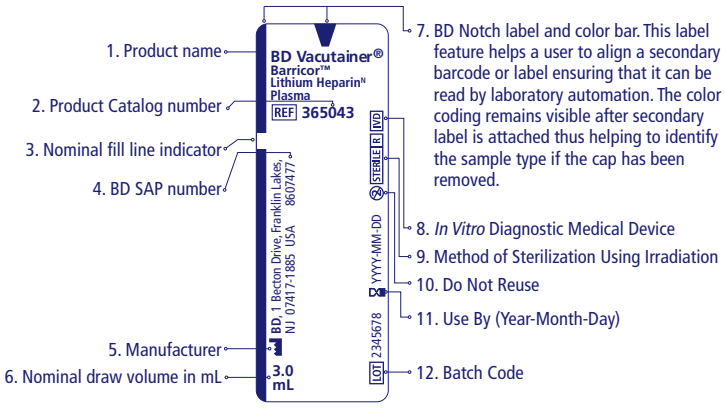
Within-tube stability has been demonstrated using the BD Barricor™ Tube for up to 24 hrs with room temperature storage and up to 7 days of refrigerated storage for all routine and special chemistry analytes except Folate (24 hrs), Glucose (18 hrs) and CO_2 (18 hrs).

ß-hCG, PSA, CKMB, Troponin I, and Troponin T were only tested for 24 hrs at room temperature and have demonstrated stability at that time point.

Within tube analyte stability has been demonstrated for therapeutic drugs for up to 48 hours of storage at room temperature and up to 7 days of refrigerated storage.

Analyte stability can be affected by a wide range of factors and should therefore be evaluated for the storage containers and conditions of each laboratory. The BD Technical Services Department is available to provide information regarding these studies.

LABELING



Symbol and Mark Key

- EC REP — Authorized Representative
- LOT — Batch Code
- REF — Catalog Number
- Do Not Reuse
- Do Not Use If Package Damaged
- Fragile, Handle With Care
- IVD — *In Vitro* Diagnostic Medical Device
- Keep Away from Sunlight
- Manufacturer
- STERILE R — Method of Sterilization Using Irradiation
- **Rx Only** — Prescription only.
- Storage Temperature Range
- This End Up
- Use By
- Recyclable
- Consult Instruction for Use

TABLE 3

BD Vacutainer® Barricor™ Plasma Blood Collection Tube

Clinical Evaluations – Routine Chemistry, Immunochemistry, TDM

Analyte	Instruments	Analyte	Instruments
Alanine Aminotransferase	6,9	Progesterone	4,10
Acetaminophen	2,12	Prostate Specific Antigen	10,14
Albumin	6,9	Rheumatoid Factor	6,9
Alkaline Phosphatase	6,9	Salicylate	2,15
Amylase	6,9	Sodium	6,9
Aspartate Aminotransferase	6,9	Testosterone	4,10
Bilirubin, Direct	6,9	Thyroid Stimulating Hormone	4,12
Bilirubin, Total	6,9	Total Protein	6,9
Blood Urea Nitrogen	6,9	Total Thyroxine	4,12
C-Reactive Protein	3,7	Total Triiodothyronine	4,5
Calcium	6,9	Transferrin	3,7
Carbamazepine	2,12	Triglycerides	6,9
Carbon Dioxide, Total	6,9	Troponin I	5,11
Chloride	6,9	Troponin T	10
Cholesterol	6,9	Uric Acid	6,9
Complement C3	1,7	Valproic Acid	2,12
Cortisol	4,10	Vancomycin	2,12
Creatine Kinase-MB fraction	5,11	Vitamin B12	8,11
Creatinine	6,9		
CK	6,13		
Digoxin	2,12		
Estradiol	4,12		
Ferritin	8,11		
Folate	8,5		
Follicle Stimulating Hormone	4,12		
Free Thyroxine	4,12		
Free Triiodothyronine	4,12		
Gamma-glutamyltransferase	6,9		
Glucose	6,9		
Haptoglobin	1,7		
High Density Lipoprotein	6,9		
Human Chorionic Gonadotropin	4,10		
Immunoglobulin A	1,7		
Immunoglobulin G	1,7		
Immunoglobulin M	1,7		
Iron	6,9		
Lactate Dehydrogenase	6,9		
Lipase	6,9		
Low Density Lipoprotein	6,9		
Luteinizing Hormone	4,12		
Magnesium	6,9		
Phenytoin	2,12		
Phosphorus	6,9		
Potassium	6,9		

1. Abbott ARCHITECT® c4000
2. Abbott ARCHITECT® ci4100™
3. Abbott ARCHITECT® c8000
4. Abbott ARCHITECT® i1000SR
5. Beckman Coulter Access® 2
6. Beckman Coulter AU680
7. Beckman Coulter UniCel® DxC 660i
8. Beckman Coulter UniCel® DxI 800
9. Roche MODULAR *ANALYTICS*
10. Roche cobas® e411
11. Siemens ADVIA Centaur® XP
12. Siemens Dimension Vista® 1500
13. Siemens Dimension® RxL
14. Ortho VITROS® ECi
15. Ortho VITROS® 4600

REFERENCES

CLSI Document GP39-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 GP41-A6. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; approved standard, 6th ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.

CLSI Document GP44-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.

TECHNICAL SERVICES

Technical Services

BD Life Sciences – Preanalytical Systems
1 Becton Drive
Franklin Lakes, NJ 07417-1885

1-800-631-0174

www.bd.com/vacutainer/contact/tech_services.asp

Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA

EC REP Becton, Dickinson and Company, Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom

Made in UK
VDP40180-02
05/2016