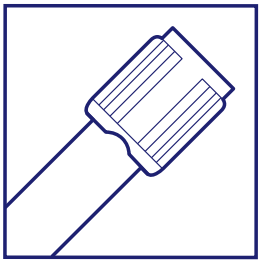
BD Vacutainer®

PPT™

Plasma Preparation Tube

For the Preparation of Undiluted Plasma
for use with Molecular Diagnostic Test Methods



REF 362788
REF 362799

Sterile Interior

REF 362788
5mL Draw Capacity
(13 x 100mm tube size)

REF 362799
8.5mL Draw Capacity
(16 x 100mm tube size)

For *In Vitro* Diagnostic Use.

INTENDED USE

The BD Vacutainer® PPT™ Plasma Preparation Tube (BD PPT™ Tube) is a plastic evacuated tube for the collection of venous blood which upon centrifugation separates undiluted EDTA plasma for use in molecular diagnostic test methods (such as but not limited to PCR - polymerase chain reaction and/or bDNA - branched DNA amplification techniques) or other procedures where an undiluted EDTA plasma specimen is required as determined by the laboratory.

SUMMARY AND EXPLANATION

Preparation of plasma from whole blood is a first step for many *in vitro* molecular diagnostic assays. The BD PPT™ Tube provides a means for collection, processing and transportation of an undiluted EDTA plasma specimen in a closed evacuated system. The tubes contain 9 mg and 15.8 mg of spray-dried K_2EDTA, yielding ratios of 1.8 mg/mL and 1.9 mg/mL of blood when the evacuated tube is filled correctly to either the 5 mL or 8.5 mL draw volume. The tube also contains a gel material that upon correct centrifugation (1,100xg for 10 minutes, swing-out rotor type centrifuge) forms a barrier between the plasma and most of the cellular elements, allowing for transportation of the BD PPT™ Tube without removal of the plasma. The result is a convenient, safe, single tube system for the collection of whole blood and the separation of plasma. Samples can be collected, processed and transported *in situ*, thereby reducing the possibility of exposure to bloodborne pathogens at the collection and sample processing sites.

STORAGE

Store unfilled tubes at 4-25ºC. Limited excursion temperatures up to 40ºC, for a cumulative time not to exceed 10 days, are acceptable.

SPECIMEN COLLECTION AND HANDLING

Required Equipment Not Provided for Specimen Collection

1. Any BD Vacutainer® Needle Holders of the standard size may be used with 13mm diameter tubes.
2. Alcohol swab for cleansing site.
3. Dry sterile gauze.
4. Tourniquet.
5. Needle disposal container for used needle or needle/holder combination.

Required Equipment Not Provided for Specimen Processing

1. Swing-out rotor type centrifuge capable of generating a relative centrifugal force of 1,100 xg (RCF) at the tube bottom.
2. 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 above.
2. All necessary tubes, identified for size, draw, and additive.
3. Labels for positive patient identification of samples.

INSTRUCTIONS FOR USE

1. Prepare venipuncture site with an appropriate antiseptic. Use your institution's recommended procedure for standard venipuncture technique and sample collection.
2. Remove needle shield.
3. Perform venipuncture.
4. Place tube in holder and push tube forward until tube stopper has been penetrated.
5. Release tourniquet as soon as blood appears in tube.
6. Wait until tube has filled to its stated volume and blood flow ceases.
7. Pull tube off needle inside holder.
8. Remove tube from holder.
9. After collection of whole blood in the BD PPT™ Tube, immediately and gently invert the BD PPT™ Tube 8 - 10 times.
10. After mixing, the whole blood specimen may be stored up to six (6) hours at room temperature until centrifugation.
11. Centrifuge BD PPT™ Tube in a balanced, swing-out rotor type centrifuge at room temperature at 1,100 RCF for a minimum of 10 minutes.
12. To obtain an undiluted plasma sample, remove the BD Hemogard™ Closure (See Instructions for Removal of BD Hemogard™ Closure Section) and decant plasma into a separate vessel or aliquot plasma into a separate vessel using a transfer pipette. NOTE: When using a transfer pipette be sure NOT to disturb the gel barrier with the tip of the pipette.

INSTRUCTIONS FOR REMOVAL OF BD HEMOGARD™ CLOSURE

1. Grasp the BD PPT™ 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: 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.

SPECIMEN STORAGE AND TRANSPORT

1. Whole blood may be stored in the BD PPT™ Tube up to six (6) hours prior to centrifugation. Centrifugation of a sample at a period greater than six (6) hours may require validation by your institution or testing laboratory. Consult assay manufacturer's recommended storage times and temperatures for EDTA anti-coagulated whole blood.

2. Plasma may be stored and transported in the BD PPT™ Tube at room or refrigerated temperatures or frozen on dry ice. Consult assay manufacturer's recommended storage times and temperatures for EDTA plasma.
3. Plasma may be stored frozen *in situ* in the BD PPT™ Tube. Freeze centrifuged BD PPT™ Tubes upright in an open wire rack at -20°C for a minimum of 2 hours. Frozen PPT Tubes can then either remain at -20°C, transferred to -70°C or lower for further storage or shipped frozen on dry ice. Users should validate their own freezing and shipping protocol for BD PPT™ Tubes. **Note: Freezing plasma *in situ* in BD PPT™ Tubes may be prohibited for assays, such as some HIV viral load tests, in which intracellular DNA interferes.**
4. Thaw the BD PPT™ Tubes in a wire rack at ambient temperature (18-25°C). When considering use of multiple freeze/thaw cycles, users should validate their own freeze/thaw protocol for BD PPT™ Tubes.

LIMITATIONS OF SYSTEM

The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Standard centrifugation conditions to generate plasma for testing do not completely sediment all cells. Accordingly, cell-based metabolism, as well as natural degradation *ex vivo* may affect plasma analyte concentrations/activities beyond acellular changes.

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).

The flow properties of the barrier material are RCF related. Optimum plasma separation and barrier formation are diminished at conditions below recommended.

Blood samples should be centrifuged within six hours of collection. Red blood cell contamination of the separated undiluted plasma sample increases with increasing delay before centrifugation. Sample stability in whole blood beyond six hours should be validated by your institution or testing laboratory.

CAUTIONS AND WARNINGS

Cautions

1. Do not use tubes if foreign matter is present
2. Do not re-use BD PPT™ Tubes.
3. Only the inside of the tube is sterile.
4. The tube is not pyrogen free.
5. Do not use BD PPT™ Tubes after expiration date printed on the tube label.
6. Since this BD PPT™ Tube contains a chemical additive (EDTA), precautions should be taken to prevent 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.
7. Separation of plasma from cells by centrifugation should take place within 6 hours of collection to prevent erroneous test results.
8. Following centrifugation some lymphocytes will remain at the plasma/gel interface.
9. Excessive centrifugation speed (over 10,000 RCF) may cause BD PPT™ Tube breakage, exposure to blood and possible injury.
10. Remove stoppers with a twist and pull motion. Removal by rolling with the thumb is not recommended.
11. After venipuncture, the top of the stopper may contain residual blood. Take proper precautions when handling tubes to avoid contact with this blood.

12. Conduct uniform handling throughout the monitoring cycle to ensure consistent results.
13. 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.
14. The spray-dried anticoagulant (K_2EDTA) has a white color.
15. 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.
16. Note: Special handling conditions may be required for assays, such as some HIV viral load tests, in which intracellular DNA interferes. Consult assay manufacturer for recommended handling conditions.
17. Note: The frozen BD PPT™ Tubes are subject to breakage upon impact. To reduce the risk of breakage during shipment, frozen tubes should be treated in the same manner as glass tubes.
18. Do not freeze tube upright in a styrofoam tray as this may cause the tubes to crack.
19. Note: Freezing plasma *in situ* in BD PPT™ Tubes may be prohibited for assays in which intracellular DNA interferes. Consult assay manufacturer for recommended transport instructions and allowable freeze-thaw cycles for EDTA plasma.
20. 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.

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 bloodborne 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 or other bloodborne pathogens. Utilize any built-in 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.
3. Discard all blood collection tubes in biohazard containers approved for their disposal.
4. Do not transfer a sample from a syringe to a tube. Additional manipulation of sharps increases the potential for needlestick injury. In addition, depressing the syringe plunger during transfer can create a positive pressure, forcefully displacing the stopper and sample and causing a 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. Tubes, with draw volume smaller than apparent dimensions indicate, may not fill to their stated volume when filled from a syringe. The laboratory should be consulted regarding the use of these samples.
5. 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.
6. Underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.

Warnings (continued)

7. 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 the centrifuge head, resulting in breakage.
8. Always allow the centrifuge to come to a complete stop before attempting to remove tubes. After the 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.

REFERENCES

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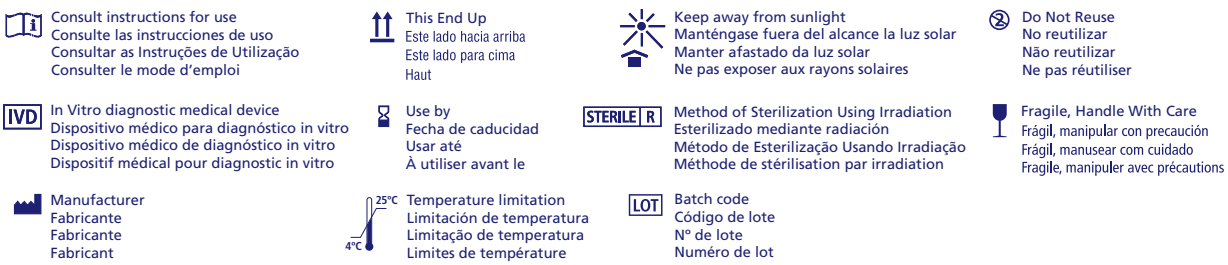
Holodniy M, Rainen L, Herman S, Yen-Lieberman B: Stability of plasma HIV viral load in Vacutainer® PPT™ Plasma Preparation Tubes during overnight shipment. 2001 J Clin Micro 38(1):323-6.

TECHNICAL SERVICES

U.S. Customers please call BD Global Technical Services at 1.800.631.0174
Customers outside the U.S. please contact your local BD sales consultant.
All customers: www.bd.com/vacutainer/contact/

BARRIER MATERIAL: GEL. SUFFICIENT K_2EDTA FOR 5 mL/8.5 mL OF BLOOD
STOPPER LUBRICATION:SILICONE.
BARRIERE: GEL. ANTICOAGULANT: K_2EDTA Q.S.P. 5 mL/8.5 mL DE SANG
BOUCHON: SILICONE.
BARRERA DE MATERIAL: K_2EDTA SUFICIENTE PARA 5 mL/8.5 mL DE SANGRE
TAPON LUBRICADO CON SILICONE
BARREIRA DE MATERIAL: K_2EDTA SUFICIENTE PARA 5 mL/8.5 mL DE SANGUE
ROLHA: SILICONIZADA

Symbol Key



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at www.bd.com/vacutainer or call 1.800. 631.0174 for a copy.

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