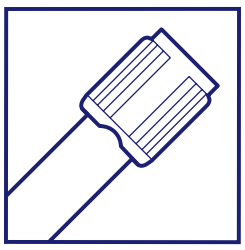
BD Vacutainer®

PPT™

Plasma Preparation Tube

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



REF 362799

Symbol and Mark Glossary:

Do Not Reuse	--	EC REP	-- Authorized Representative
REF -- Catalog Number		IVD	-- In Vitro Diagnostic Medical Device
Consult Instructions For Use	--	STERILE R	-- Method of Sterilization Using Irradiation
Use By	--	°c	-- Temperature Limitation
LOT -- Batch Code			
Manufacturer	--		-- Keep Away From Sunlight

at www.bd.com/vacutainer or call 1.800.631.0174 for a copy or consult local representative.
Becton, Dickinson and Company, Franklin Lakes, NJ USA

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Made in USA
07/08

BD Vacutainer® PPT™ - PLASMA PREPARATION TUBE
for Molecular Diagnostic Test Methods
Sterile Interior.
8.5mL Draw Capacity
(16x100mm Tube Size)

REF 362799
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 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 plasma specimen is required as determined by the laboratory.

PRINCIPLE OF PROCEDURE
The BD PPT™ Tube provides a means for collection, processing and transportation of an undiluted plasma specimen in a closed evacuated system. The tube contains 15.8 mg of dried K_2 EDTA, yielding a ratio of 1.9 mg/mL of blood when the evacuated tube is filled correctly to its 8.5 mL draw volume. The tube also contains a material that upon correct centrifugation (1,100xg for 10 minutes) 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. Only the inside of the tube is sterile. The tube is not pyrogen free.

SUMMARY AND EXPLANATION
Isolation of plasma from whole blood is a first step for many in-vitro molecular diagnostic assays. Although one definition of plasma is "acellular", a current accepted technique for plasma separation is to collect whole blood into an EDTA or ACD blood collection tube, such as the BD Vacutainer® tube containing those anticoagulants. This anticoagulated blood, collected by routine phlebotomy, requires centrifugation to separate the plasma from the formed elements. Immediately after centrifugation, the tube is opened and the plasma is carefully pipetted into a separate container.

The BD PPT™ Tube combines a spray-dried anticoagulant and a polyester material which separates most of the erythrocytes and granulocytes, and some of the lymphocytes and monocytes away from the supernatant. Plasma prepared in a BD PPT™ Tube may contain a higher concentration of platelets than that found in whole blood. 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.

WARNINGS AND PRECAUTIONS FOR *IN VITRO* DIAGNOSTIC USE
1. Do not re-use BD PPT™ Tubes.
2. Do not use BD PPT™ Tubes after expiration date printed on the tube label.
3. Since this BD PPT™ Tube contains a chemical additive (EDTA), precautions should be taken to prevent possible backflow from the tube during blood drawing (See Prevention of Backflow section).
4. Excessive centrifugation speed (over 10,000 RCF) may cause BD PPT™ Tube breakage, exposure to blood and possible injury.
5. Conduct uniform handling throughout the monitoring cycle to ensure consistent results.
6. The Spray-dried anticoagulant (K_2 EDTA) has a white color.

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. 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.
3. Discard all blood collection tubes in biohazard containers approved for their disposal.
4. Transferring a sample from a syringe to a tube is not recommended. 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.

7. **Centrifugation:**
   BD PPT™ Tubes will withstand up to 10,000 RCF in a balanced swing-out rotor type 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.

   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. Balance tubes to minimize the chance of breakage. Match tubes with 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, and BD Vacutainer® Plastic tubes with Plastic tubes.

   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.

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

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 16mm diameter tubes.
3. Alcohol swab for cleansing site.
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. Centrifuge capable of generating 1100 xg (RCF) at the tube bottom.
2. Gloves and other personal protective equipment as necessary for protection from exposure to bloodborne pathogens.

PROCEDURE
1. The BD PPT™ Tube should be at room temperature and properly labeled for patient identification.
2. Collect blood into the BD PPT™ Tube using your institution's recommended procedure for standard venipuncture technique and sample collection.
3. After collection of whole blood in the BD PPT™ Tube, gently invert the BD PPT™ Tube 8 - 10 times.
4. After mixing, store the BD PPT™ Tube upright at room temperature until centrifugation. Blood samples should be centrifuged within two (2) hours of blood collection for best results. Centrifugation of a sample at a period greater than 2 hours may require validation by your institution or testing laboratory. Centrifuge BD PPT™ Tube/blood sample at room temperature at 1,100 RCF (Relative Centrifugal Force) for a minimum of 10 minutes.
5. 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 barrier with the tip of the pipette.
6. Refer to the Kit or Assay Manufacture's Instructions for Sample Handling.

SPECIMEN COLLECTION and HANDLING
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.

Prevention of Backflow
Since BD PPT™ Tubes contain a chemical additive, 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.

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.

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 relative centrifugal force (RCF) - related. Optimum plasma separation and barrier formation are diminished at conditions below recommended.

Blood samples should be centrifuged within two 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 2 hours should be validated by your institution or testing laboratory.

TECHNICAL SERVICE

Technical Service may be reached at (800) 631-0174. You may write to BD Vacutainer® for further information at:

Technical Service
BD Vacutainer®
1 Becton Drive
Franklin Lakes, NJ 07417-1885

Whenever changing any manufacturer's blood collection tube type or size for a particular laboratory assay, the Laboratory Director should review the tube manufacturer's data and/or previous data generated to establish/verify your reference range data for your specific instrument and reagent system. Based on such information, the laboratory can then decide if changes are indicated.

BARRIER MATERIAL: SUFFICIENT K_2 EDTA FOR 8.5 mL OF BLOOD / STOPPER LUBRICATION: SILICONE.

BD Diagnostics - Preanalytical Systems • Franklin Lakes, NJ						
REV LEVEL	**ALOA #**	**ECO #**	**DESCRIPTION**	**DESIGNER**	**DATE**	**SAP #**
01	00353-01	ECO84797	Release new art - WEB Only	D. Peterson	7/16/08	na
PACKAGING LEVEL			**PRODUCT CIRCULAR - WEB ONLY**	**DRAWING #**	**VDP40145-01**	