



BD P100

Blood Collection System

for Plasma Protein Preservation

For Research Use Only

Not For Use in Diagnostic Procedures

INTENDED USE

BD™ P100 is a Blood Collection System with a integrated mechanical separator that provides a means for collection, separation, transportation and preservation of plasma to be used in protein analysis. This product is for research use only and therefore the use of this product for diagnostic procedures and subject management is strictly prohibited. Neither the clinical utility nor the performance characteristics of the tube as part of an in vitro diagnostic procedure has been established.

PRODUCT DESCRIPTION

The BD P100 Tube contains spray-dried K2EDTA anticoagulant and proprietary additives. During centrifugation, the separator device is activated and moves into position between the plasma and cellular elements. After separation, plasma may be aspirated directly from the collection tube, eliminating the need to transfer the plasma to a secondary tube.

BLOOD COLLECTION AND HANDLING

Required Equipment Not Provided

1. **Blood Collection Set with 12 inch tubing** such as the BD Vacutainer® Safety-Lok™ or BD Vacutainer® Push Button Blood Collection Set.
2. A BD Vacutainer® Holder such as the BD Vacutainer® One Use Holder must be used to ensure proper function.
3. Disposable transfer pipettes if direct sampling from the instrument is not used or if the specimen is stored separately.
4. Centrifuge capable of generating 1100 – 3000 g at the bottom of the tube.
5. Gloves, eye protection and other personal protective equipment as necessary for protection from exposure to blood borne pathogens.

Prevention of Backflow

The BD P100 blood collection tube contains chemical additives. It is important to avoid possible backflow from the tube, with the possibility of adverse subject reaction. To guard against backflow observe the following precautions:

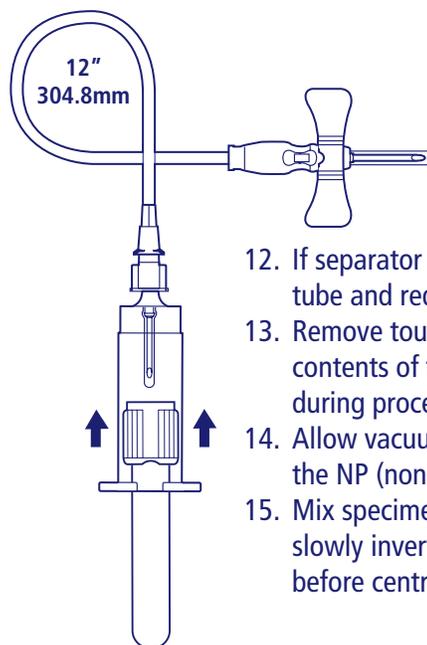
1. Use a blood collection set such as the BD Vacutainer® Safety-Lok™ or BD Vacutainer® Push Button Blood Collection Set.
2. Place limb in a downward position.
3. Hold tube with stopper upper-most.
4. Release tourniquet as soon as blood starts to flow into the tube.
5. Make sure that tube additives do not touch the stopper or the end of the needle during venipuncture.

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 lyophilized additives (e.g., BD Vacutainer®, Heparin, EDTA, Plasma BD P100, or Serum Tubes)
5. Tubes with other liquid additives (e.g. PAXgene® Tubes)

Venipuncture Technique and Specimen Collection General Instructions

1. It is absolutely essential to use a 12 inch blood collection set, when collecting blood using this device such as BD Vacutainer® Safety-Lok™ or BD Vacutainer® Push Button Blood Collection Set.
2. Wear gloves during venipuncture and when handling blood collection tubes to minimize exposure hazard.
3. Select tube or tubes for required specimen.
4. Assemble a blood collection set with 12 inch tubing into a BD Vacutainer® One Use Holder. Be sure that blood collection set is firmly attached to holder and does not unthread during use.
5. Place tube into holder. Note: Do not puncture stopper.
6. Select site for venipuncture.
7. Apply tourniquet. Prepare venipuncture site with appropriate antiseptic. Do not palpate venipuncture site after cleansing.
8. Place subject's limb in a downward position.
9. Remove needle shield. Perform venipuncture with limb downward and tube stopper up (refer to the Prevention of Backflow section).
10. Center tubes in the holder, to prevent sidewall penetration and resultant premature vacuum loss.
11. Push tube onto non-patient-end (NP-end) of needle in one **swift action** in order to minimize premature separation of the mechanical separator from the stopper. Hold tube on NP-end during drawing.



12. If separator moves in the tube during blood collection, discard the tube and redraw.
13. Remove tourniquet as soon as blood appears in tube. Do not allow contents of the tube to contact the stopper or end of the needle during procedure.
14. Allow vacuum to be exhausted prior to removing the tube from the NP (non-patient) end of the needle.
15. Mix specimen with tube additives. For optimal mixing, slowly invert tube 8 to 10 times immediately after blood collection before centrifugation.

Centrifugation

To achieve the lowest platelet count, refer to the recommended centrifugation conditions outlined in the following table.

RCF (g)	Time (min)
1100	30
1600	30
2500	20

The tube will withstand up to 3000 g in a balanced centrifuge.

Relative Centrifuge Force (g) is related to centrifuge speed setting (rpm) using either of the following equations: where "r" expressed in cm, is the radial distance from the center of the centrifuge head to the bottom of the tube.

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

Instructions for Removal of BD Vacutainer® Hemogard™ Closure

1. Grasp the BD P100 Tube with one hand, placing the thumb under the BD Hemogard™ Closure. (For added stability, place limb on solid surface.) With the other hand, twist the 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 the tube. **Caution: Any tube has the potential to crack. If the tube contains blood, an exposure hazard exists.** To help prevent injury during 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 Hemogard™ Closure is loosened.
3. Lift closure off the tube. In the unlikely event of the plastic shield separating from the rubber stopper, **DO NOT REASSEMBLE THE CLOSURE.** Carefully remove stopper from the tube.

Storage

Store tubes at 4-25 °C (39-77 °F) unless otherwise noted on the package label. It is recommended to store the tubes in the original sealed packaging until use. The pouch with desiccant provides a moisture barrier to preserve the potency of the additives.

WARNINGS AND PRECAUTIONS

1. It is absolutely essential to use a 12 inch blood collection set, when collecting blood using these tubes such as BD Vacutainer® Safety-Lok™ or BD Vacutainer® Push Button Blood Collection Set.
2. Irritating to eyes, respiratory system and skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves and eye/face protection.
3. Do not re-use the tube.
4. Since this tube contains chemical additives (anti-coagulant and a lyophilized additive) precautions should be taken to prevent possible backflow from the tube during blood drawing (see Prevention of Backflow section and refer to the MSDS for chemical precautions).
5. Excessive centrifugation speed (over 10,000 g) may cause tube breakage, exposure to blood and possible injury.
6. Storage of tubes containing blood at or below 0 °C may result in breakage.
7. Do not remove closure by rolling with thumb. Remove with a twist and pull motion (see Instructions for Removal of the BD Hemogard™ Closure section).

- Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

CAUTION:

- 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 blood borne pathogens.
- 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 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 resheilding used needles. However, the policies and procedures of your facility may differ and must always be followed.
- Discard all blood collection "sharps" in biohazard containers approved for their disposal.
- 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.
- Transferring samples from syringe to an 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.
 - 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.
- 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.
- Overfilling or underfilling of tubes will result in incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
- Allow the BD P100 Tube to come to room temperature before use.

SYMBOL & MARK KEY:



--- Do Not Reuse



--- Manufacturer



--- Catalog Number



--- Keep Away From Sunlight



--- Batch Code



--- Temperature Limitation



--- Consult Instructions For Use



--- Use by



--- Method of Sterilization Using Radiation