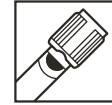


BD P800

Blood Collection System for Plasma Metabolic Biomarker Preservation

For Research Use Only
Not for Use in Diagnostic Procedures



INTENDED USE

BD P800 is an evacuated blood collection tube that provides a means for collection and preservation of plasma metabolic markers such as Glucagon-like Peptide-1 (GLP-1), Glucagon, Ghrelin and Gastric Inhibitory Polypeptide (GIP). 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 P800 tube contains spray-dried K₂EDTA anticoagulant and proprietary additives.

BLOOD COLLECTION AND HANDLING

Required Equipment

1. Blood Collection Set with 12 inch tubing such as the BD Vacutainer® Push Button Blood Collection Set or BD Vacutainer® Safety-Lok™ Blood Collection Set.
2. A BD Vacutainer® Needle Holder such as the BD Vacutainer® One Use Holder must be used to ensure proper function.
3. Centrifuge capable of generating 1000 – 3000 g at the bottom of the tube.
4. Gloves, eye protection and other personal protective equipment as necessary for protection from exposure to blood borne pathogens.

Prevention of Backflow

The BD P800 Evacuated 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® Push Button Blood Collection Set or BD Vacutainer® Safety-Lok™ 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 for coagulation studies (e.g., citrate)
3. BD SST™ and Serum Tubes
4. Tubes with other dry additives (e.g., BD Vacutainer®, Heparin, EDTA, or Plasma BD P800)
5. Tubes with other liquid additives (e.g. PAXgene®)

Venipuncture Technique and Specimen Collection General Instructions

1. It is absolutely essential to use a 12 inch blood collection set, such as BD Vacutainer® Push Button Blood Collection Set or BD Vacutainer® Safety-Lok™ 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. Allow the BD P800 Tube to come to room temperature before use.
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 subject's limb in a downward position.
6. Select site for venipuncture.
7. Apply tourniquet. Prepare venipuncture site with appropriate antiseptic. Do not palpate venipuncture site after cleansing.
8. Place tube into holder. Note: Do not puncture stopper.
9. Remove needle shield. Perform venipuncture with limb downward and tube stopper upper-most (refer to the prevention of back flow 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. Hold tube on NP-end during drawing.
12. 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.
13. Allow vacuum to be exhausted prior to removing the tube from the NP-end of the needle.
14. Mix specimen with tube additives. For optimal mixing, slowly invert tube 8 to 10 times immediately after blood collection before centrifugation.

Centrifugation

Recommended centrifugation RCF (g's) and time is 1100 – 1300 RCF for 10 and 20 minutes respectively for the 2.0 and 8.5 mL tubes in a swing type centrifuge. The tube will withstand up to 3,000 RCF 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.

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

Instructions for Removal of BD Vacutainer® Hemogard™ Closure

1. Grasp the BD P800 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 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 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 BD 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 2-8 °C (≈39 °F) unless otherwise noted on the package label. It is recommended to store the tubes in the original packaging until use.

WARNINGS AND PRECAUTIONS

1. It is absolutely essential to use a 12 inch blood collection set, such as BD Vacutainer® Push Button Blood Collection Set or BD Vacutainer® Safety-Lok™ Blood Collection Set, when collecting blood.



Contains Dipotassium EDTA <100%; Tacrine <20%

- Warning**
Harmful if swallowed or if inhaled. Harmful in contact with skin. Causes skin irritation. Causes serious eye irritation. Suspected of causing cancer. Obtain special instructions before use. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation occurs: Get medical advice/attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF exposed or concerned: Get medical advice/attention.
2. Do not re-use the tube.
 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).
 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).
 8. Compatibility of the 16x100mm BD P800 tube fitted with a Hemogard™ Closure, with some manufacturers' fixed angle centrifuges requires that the tube holders for these centrifuges be fitted with appropriate length cushions. These cushions raise the tube in the centrifuge tube holder so that the bottom of the Hemogard™ Closure is positioned slightly above the opening of the tube holder. Positioning of the BD P800 tube within the holder in this manner will prevent loosening or dislodgement of the stopper/Hemogard™ Closure from the tube, during centrifugation.
 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.

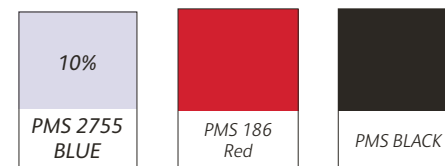
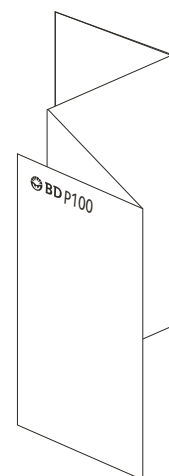
CAUTION

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. 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 safety engineered feature, 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.
3. Discard all blood collection "sharps" in biohazard containers approved for their disposal.
4. 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.
5. Transferring samples from syringe to an evacuated tube using a non-sharps device should be performed with caution for the following reasons: • 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.
6. If blood is collected through an intravenous (IV) line, ensure that line has been cleared of IV solution. This is critical to avoid erroneous laboratory data from IV fluid contamination. **Direct draw of the BD P800 Tube from an IV line must be avoided.**
7. Safer transfer of blood from a syringe into an evacuated blood collection tube can be accomplished by attaching a BD Vacutainer® Blood Transfer Device (REF 364880). This device can be used after: • Blood is collected into the syringe without using a needle • Blood is collected into a syringe using a safety-engineered hypodermic needle (BD Eclipse™ Needle) • Blood is collected into a syringe using a safety-engineered winged collection set (BD Vacutainer® Push Button Blood Collection Set or BD Vacutainer® Safety-Lok™ Blood Collection Set).
8. Overfilling or underfilling of tubes will result in incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
9. Allow the BD P800 Tube to come to room temperature before use.

SYMBOL KEY:

REF	--- Catalog Number	Do Not Reuse
LOT	--- Batch Code	Consult Instructions For Use
Manufacturer	--- Manufacturer	Keep Away From Sunlight
Use by	--- Use by	Temperature Limitation
STERILE R	--- Method of Sterilization Using Radiation	

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Tint used in "Prevention of Backflow" Section

GRAPHICS AND TEXT IS PRINTED IN PMS BLACK

FOR WARNING GHS SYMBOLS - WARNING SYMBOL PRINT PMS BLACK WITH PMS 186 RED AS THE OUTSIDE SQUARE AND ITS RESPECTED TEXT PRINT PMS BLACK

GRAPHICAL DIMENSIONS AND LOCATION MUST ADHERE TO ELECTRONIC FILE REQUIREMENT.

SIZE 6.75" X 17" ONE SIDE

BD Preanalytical Systems • Franklin Lakes, NJ						
REV LEVEL	ALO #	ECR/O #	DESCRIPTION	DESIGNER	DATE	SAP #
01-04	Refer to archived version/s of this document for description of prior rev level/s, ECO#/s incorporated revision/s, designer/s, date/s and SAP#/s.					
05	00847-01	ECR/O 5-44873	Update Logo. Update copyright statement. Add full zip code. Update revision date. Remove patent information. New SAP#.	STOECKMANN	02/26/16	500014765
06	00883-01	ECR/O 5-70048	Added Endotoxin statement in warnings and precautions section. SAP# updated. Updated the revision month.	A. VASANTH	07/01/16	500016792
07	01031-02	ECR/O 5-122606	Fonts changed to "FS Albert Pro" family. In "WARNINGS AND PRECAUTIONS" 2nd point "Harmful by inhalation and if swallowed. 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 protective clothing." replaced with updated Warning GHS Symbols & its description. PMS 186 Red & PMS BLACK swatches added. Copyright statement year updated to 2018. Graphics and text is printed in PMS Black. Warning symbol prints PMS Black with PMS 186 Red as the outside square. Removed the swatch PMS 2755 Blue. Removed www. From "bd.com/proteomics" which is also made in bold. Updated byline statement as per BD standards. Updated "do not reuse" symbol.	ADITYA SRIKANTH	08/Feb/2019	500031312
PACKAGING LEVEL			Product Circular	DRAWING #	VDP40148-07	