Whole Blood Collection Set
40010

DRAFT

Last Updated December 1, 2008

DESCRIPTION

The collection set includes a needle with needle cover, a needle guard, a tube holder, a 500 mL Whole Blood collection bag with 70 mL Citrate Phosphate Dextrose (CPD) anticoagulant, and a sample/diversion pouch for the collection of unanticoagulated donor blood samples for laboratory testing; the collection set is 100% latex free.

Tubing dimensions of the collection set are an inner diameter of 0.116", an outer diameter of 0.160", and a wall thickness of 0.22".

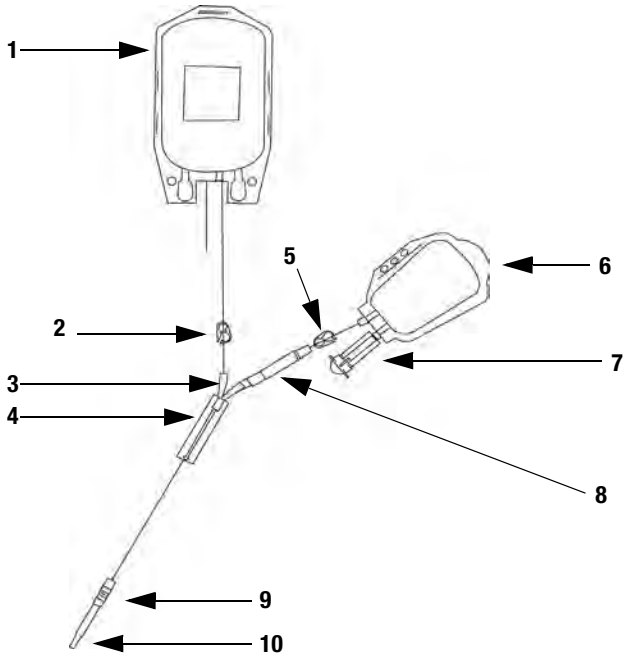
INDICATIONS FOR USE

The collection set is intended for a single Whole Blood collection of 500 mL ± 10%.

WARNINGS AND CAUTIONS

- The collection set is for single use only.
- Use aseptic technique throughout all procedures to ensure product quality.
- The solution should be clear. Do not use the collection set if the solution is cloudy or if the solution contains particulates.
- Inspect the outer aluminum foil pouch that contains the collection set for damage. Do not use the collection set if you find holes or tears in the outer aluminum foil pouch.
- If any of the following occurs in a packaged collection set, do not use the collection set:
  - There are any holes or tears in the collection set packaging.
  - The collection set is defective or damaged.
  - The collection set is incorrectly assembled.
  - The tubing has severe kinks.
  - Any clamps are closed.
  - The frangible connector is broken.
  - Anticoagulant is present in the sample pouch.
- The blood and fluid pathways of the collection set are steam sterilized and are nonpyrogenic. It is normal to have condensation in the outer aluminum foil and individual packages. If the amount of moisture is greater than expected, check for leaks from the fluid-filled components of the collection set.
- Always inspect the collection set for leaks before use.
- Protect Whole Blood Collection Sets from freezing and excessive heat during storage.
- Due to possible exposure to the hepatitis virus, the human immunodeficiency virus, and other infectious agents in the handling of blood, take adequate precautions at all times to prevent exposure to, and transmission of, such agents.
- For processing the CPD Whole Blood unit on the Atreus machine:
  - After collection, hold the CPD Whole Blood in an environment that allows the blood to continuously cool towards 18–28°C for at least 2 hours before processing the Whole Blood on the Atreus system.
  - Sterile connect the Whole Blood Collect Set onto an Atreus Processing Set.
  - Complete Atreus processing within 8 hours of collection.
- Dispose of all biohazardous waste according to your institution’s Standard Operating Procedure (SOP).
- Rx Only. Federal law (USA) restricts this device to sale by or on the order of a physician.

FEATURES OF THE COLLECTION SET



1. Whole Blood bag containing CPD anticoagulant
2. Collection line clamp
3. Y connector
4. Needle guard
5. Colored sample/diversion line clamp
6. Sample/diversion pouch
7. Tube holder
8. Frangible connector
9. Needle hub
10. Needle with needle cover

Figure 1: Atreus Collection Set

INSTRUCTIONS FOR USE

Note: Label the Whole Blood bag and the donor blood samples according to your institution's SOP to ensure accurate identification of the product.

1. Inspect the collection set.
2. Perform the following actions in any order:
   - Load the bags onto a scale or blood mixer, according to the device manufacturer's recommendations.
   - Close the collection line clamp.
   - Break the frangible connector in the line to the sample/diversion pouch.

Caution: When you break frangible connectors, bend them in both directions to make sure you break them completely. Failure to do so may result in restricted blood flow.

3. Prepare the venipuncture site according to your institution's SOP.

Warning: Prepare the donor arm using a method that minimizes the potential for bacterial contamination of the collected product.

4. Perform venipuncture according to your institution's SOP.
5. Stabilize the needle to the donor's arm according to your institution's SOP.
6. Allow the desired volume of donor blood to flow into the sample/diversion pouch. Positioning the sample/diversion pouch equal to or below the donor's arm may assist with blood flow.
7. Close the colored sample/diversion line clamp.
8. Open the collection line clamp to allow the donor blood to flow into the Whole Blood bag.
9. Mix the Whole Blood and CPD in the Whole Blood bag at several intervals during collection.

10. Permanently seal the sample/diversion line according to your institution's SOP and as near to the Y connector as possible.
11. Transfer donor blood samples from the sample/diversion pouch, using evacuated blood collection tubes, within approximately four minutes of venipuncture to avoid possible clot formation in the sample/diversion pouch.
12. Collect the appropriate volume of Whole Blood as indicated on the Whole Blood bag packaging ± **10%.**
13. Before withdrawing the needle, permanently seal the collection line tubing according to your institution's SOP and as near to the Y connector as possible.
14. Withdraw and shield the needle according to your institution's SOP.

Warning: **To ensure that the needle guard engages into the locked position, hold it firmly while you remove the needle and pull the tubing until two clicks occur.**

15. Disconnect the needle and sample/diversion pouch at the seal on the collection line tubing.
16. Dispose of the needle and sample/diversion pouch according to your institution's SOP.
17. Immediately strip the Whole Blood remaining in the collection line tubing into the Whole Blood bag, mix the product, and refill the tubing.
18. Repeat step 17 at least once.

RETURN OF USED PRODUCT

If for any reason this product must be returned to CaridianBCT, Inc. a returned goods authorization (RGA) number is required from CaridianBCT prior to shipping. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and a RGA number may be obtained from the CaridianBCT Quality Assurance department.

Caution: **It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment.**

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