

Blood Collection and Specimen Processing Guide

Collecting and Preparing Blood Specimens for the Epi proColon® Test

Blood Collection Procedure

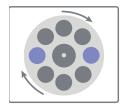
Blood should be collected according to your laboratory's procedure for venipuncture using **ONLY** BD Vacutainer® 10 mL K2EDTA (lavender top) blood collection tubes. Blood collection tubes should be allowed to complete the evacuated fill to ensure the required 3.5 mL of plasma is obtained.

Whole blood may be stored refrigerated or at room temperature (2°C to 30°C). Plasma preparation should be performed within 4 hours after blood is collected. **Do not freeze whole blood specimens.**



Plasma Sample Preparation

Plasma preparation should be performed within 4 hours after drawing blood. Disable the brake function in the centrifuge to prevent disruption of the cell layer. Label all tubes with appropriate patient identification information.



STEP 1:

Centrifuge the labeled patient's blood collection tube for 12 minutes at 1350 +/- 150 rcf. (For conversion of rcf to

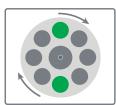
RPM, refer to the centrifuge manufacturer's user manual).



STEP 2:

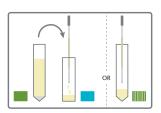
Remove the blood collection tube from the centrifuge.

Using a fresh 6 inch disposable transfer pipette, transfer the clear plasma to a labeled 15 mL conical polypropylene centrifuge tube, taking care not to transfer blood cells.



STEP 3:

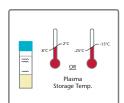
Centrifuge labeled conical tube plasma sample for 12 minutes, at the same speed as in Step 1.



STEP 4:

Using a fresh 9 inch disposable transfer pipette, transfer the minimum of 3.5 mL plasma to a clean, labeled cryovial for storage, or to a labeled 15 mL conical polypropylene centrifuge tube for immediate sample analysis.

Take care not to transfer any of the buffy coat sediment now found in the bottom of the tube.



STEP 5:

Store the labeled plasma sample as indicated under Sample Storage and Transport Requirements below.

Precautions

- The brake function must be disabled on the centrifuge prior to use.
- Use ONLY BD Vacutainer® 10 mL K2EDTA (lavender top) blood collection tubes. Blood collection tubes should be allowed to complete the evacuated fill to ensure the required 3.5 mL of plasma is obtained. Other manufacturer's collection tubes have not been validated for use with this test.
- Do not freeze whole blood samples.
- Hemolyzed plasma specimens are unacceptable for use. If hemolysis is observed, discard and obtain a new patient blood specimen for testing (Step 2).
- After centrifuging the plasma, take care not to transfer the buffy coat sediment in the bottom of the conical centrifuge tube to the clean cryovial or conical tube for storage (Step 4).

All patient blood and plasma specimens should be handled as
though they are capable of transmitting disease. Use universal
precautions specified in the OSHA Bloodborne Pathogen Standard
and CLSI document No. M29-A3. Dispose of blood collection tubes
in biohazardous containers in accordance with federal, state and local
regulations. Use of protective gloves is recommended.

Sample Storage and Transport Requirements

- After plasma has been centrifuged and separated into a labeled tube, plasma samples may be stored refrigerated at 2°C to 8°C for up to 72 hours or frozen at -15°C to -25°C for up to 14 days.
- Transport of shipment of plasma samples should follow the same temperature and time requirements as listed above.
- Frozen plasma samples should be transported on dry ice or equivalent to ensure samples do not thaw during transit.



Blood Collection and Specimen Processing Guide

Materials and Equipment Needed at Your Draw Station

Equipment Required

Bench top centrifuge to accommodate BD Vacutainer® 10 mL K2EDTA (lavender top) blood collection tubes.

Laboratory Consumables Required	Suggested Manufacturer Information
6 inch disposable transfer pipettes, ~5 mL capacity	Samco® graduated 1 mL large bulb, non-sterile pipettes, Thermo Scientific Cat. No. 222, or equivalent
9 inch or longer disposable transfer pipettes, ~5 mL capacity	Samco® extra-long transfer pipettes, Thermo Scientific, Cat. No. 262, or equivalent
15 mL polypropylene conical bottom centrifuge tubes, sterile	Sarstedt Cat. No. 62.554.502, or equivalent
Cryovials of sufficient size to contain 3.5 mL to 4.0 mL plasma	VWR Cat. No. 89094-812, or equivalent

References

Epi proColon® Test Instructions for Use (IFU 0008), current revision

- Section 4, Precautions and Safety
- Section 7, Materials Required, but not Provided
- Section 8, Specimen Collection and Handling

epigenomics

Epigenomics, Inc. USA

844 537 4669 (844-5-EPI NOW)

+1 240 747 7002

+1 240 747 7052

support.us@epigenomics.com www.epigenomics.com