

Title	Blood Processing and Storage for Clinical Trials
SOP Code	SOP204_01
Effective Date	01-Sep-2012

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes how blood should be processed and stored to ensure high quality and high integrity specimens for research. The SOP does not cover detailed safety procedures for handling Human Biological Materials (HBMs) or hazardous chemicals.

2.0 SCOPE

Blood specimens are drawn from patients that have been through the informed consent process and agreed to participate in a clinical trial. Blood and blood components can be used in clinical trials for establishing the pharmacokinetics profile of a drug, pharmacodynamics, or pharmacogenomics.

3.0 RESPONSIBILITIES

This SOP applies to clinical research personnel involved in blood processing and storage. Roles and responsibilities may vary at specific sites. Blood specimens must be processed by qualified personnel. Personnel must follow institutional biosafety guidelines.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

5.1 Blood Processing - General

- 5.1.1 Collect blood into required type and number of tubes, as per protocol or other study document.
- 5.1.2 Verify that the specimens are adequately labelled, prior to processing.
- 5.1.3 Record time of blood collection, time of blood processing, time of aliquot freezing, and any deviations from the protocol. This information may be required for downstream analysis of blood components.
- 5.1.4 Take samples to designated processing area.
- 5.1.5 Process blood, according to the timelines described in the study protocol, or other study document.
- 5.1.6 Process into serum, plasma, and and/or buffy coat, if/as specified. Serum should be processed after one hour, to allow complete coagulation. Plasma and buffy coat should be processed within 30 minutes of collection.
- 5.1.7 Follow the processing steps described below, unless otherwise specified in the protocol, or other study document.

5.2 Separation of Plasma

- 5.2.1 Fractionate the whole blood, collected in tubes containing an anticoagulant such as EDTA or Heparin, by centrifuging at 1500-2000 x g for 15 minutes, at room temperature.
- 5.2.2 This will separate the blood into three visible layers (see Figure 1):
 - The upper layer is generally clear and pale yellow in colour.
 - The second layer is a narrow grayish white interface band representing the “buffy coat” or leukocyte fraction.
 - The third/bottom layer is dark red, and consists of the erythrocytes (red blood cells).

Appearance of Blood Samples during Recovery of WBCs

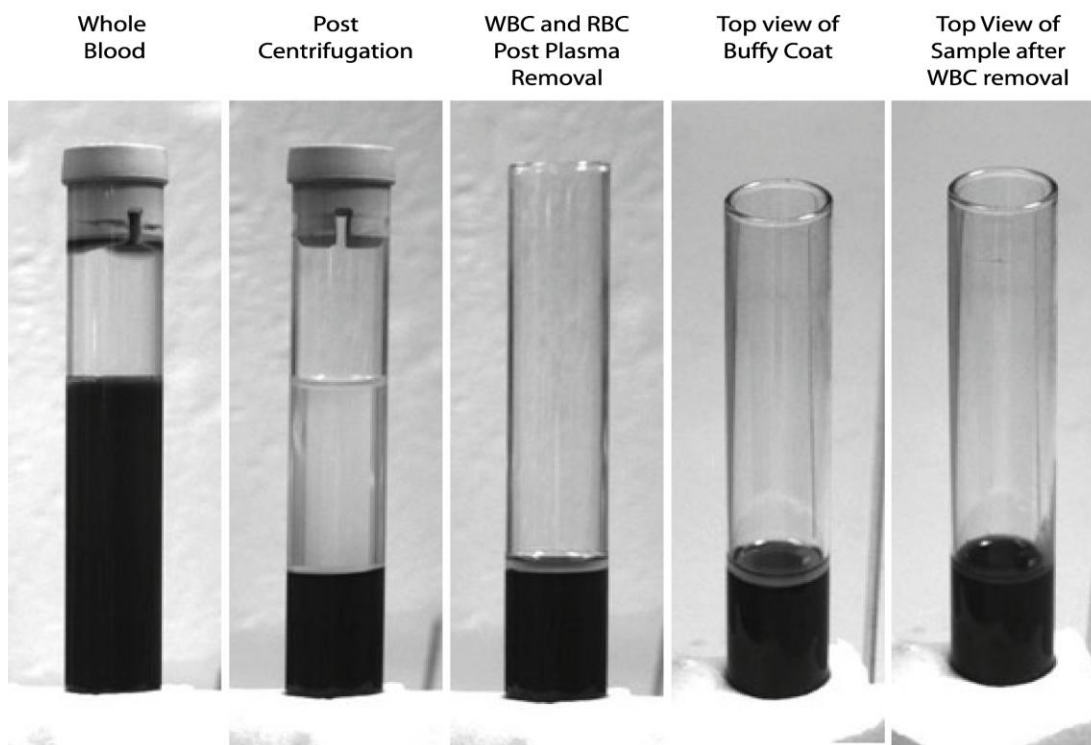


Figure 1: Blood Separation for White Blood Cells in Buffy Coat.

- 5.2.3 Using a disposable transfer pipette, aspirate off the plasma layer down to approximately 1 mm from the buffy coat layer. Take care not to disturb the leukocyte/buffy coat layer.
- 5.2.4 Expel all plasma from the pipette into a plasma collection tube.
- 5.2.5 Aliquot recovered plasma into labelled cryovial(s).
- 5.2.6 Place the cryovial(s) in dry ice until freezer storage.
- 5.2.7 Transfer the cryovial(s) to a labelled freezer storage box, and place the box immediately in the -80° C freezer or in liquid nitrogen.
- 5.2.8 Record exact storage location of the cryovial(s).

5.3 Recovery of White Blood Cells (aka, Leucocyte or Buffy Coat)

- 5.3.1 After removing the plasma layer, use a transfer pipette used to aspirate all of the buffy coat layer (usually 0.5 mL or less from 10ml of whole blood).
- 5.3.2 Expel the buffy coat into a single labelled cryovial then take half the specimen and store in a separate labelled cryovial.
- 5.3.3 Place the cryovial(s) in dry ice until freezer storage.
- 5.3.4 Transfer the cryovial(s) to a labelled freezer storage box and place the box immediately in the -80° C freezer or in liquid nitrogen.
- 5.3.5 Record the exact storage location of cryovial(s).

5.4 Separation of Serum

- 5.4.1 Collect the whole blood in serum collection tubes coated with particles such as silica, which act as a clotting activator.
- 5.4.2 Invert the tubes 8 times immediately following collection, to ensure proper coagulation.
- 5.4.3 Incubate the mixed serum tubes for one hour at room temperature, to ensure complete coagulation.
- 5.4.4 Following incubation, centrifuge the serum tubes at 1500 g for 15 minutes.
- 5.4.5 Aspirate the supernatant, and transfer directly into labelled cryovial(s).
- 5.4.6 Place the cryovial(s) on dry ice until freezer storage.
- 5.4.7 Transfer tubes to a labelled freezer storage box, and place the box in a -80° C freezer or in liquid nitrogen.
- 5.4.8 Record the exact storage location of cryovial(s).

6.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

2011 NCI Best Practices for Specimen Resources. Office of Biorepositories and Biospecimen Research, National Cancer Institute, Bethesda, MD.
<http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf>

ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research. Cell Preservation Technology 6(1), 3-58, 2008 <http://www.isber.org/Pubs/BestPractices2008.pdf>

CTRNET Standard Operating Procedures, Canadian Tumour Repository Network,
<http://www.ctrnet.ca/operating-procedures>



7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP204_01	01-Sep-2012	Original version