
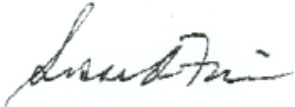


Title:	Umbilical Cord Blood Collection Standard Operating Procedure		
Origination Date:	16 Apr 2012	Total Pages:	8
Effective Date:	18 Jan 2013	SOP Number	LTC-SOP-63 v1.0
Prepared By:	ACTG/IMPAACT Lab Tech Committee	Supersedes SOP	N/A
	Adapted from The PROMISE CBCM MOP	Dated:	

	Network	Name, Title	Signature	Date
Approved By (Network):	ACTG	Robert W. Coombs, MD, PhD, FRCPC ACTG Network Laboratory Principal Investigator		06Nov2012
	IMPAACT	Susan Fiscus, PhD IMPAACT Network Laboratory Principal Investigator		18Jan2013

	Name, Title	Signature	Date
Reviewed By (Laboratory):			

Revision History	Version	Effective Date (dd/mmm/yy)	Comments

Table of Contents

1	Purpose	3
2	Scope	3
3	Background.....	3
4	Authority and Responsibility	3
5	Reagents and Materials.....	4
6	Biosafety.....	4
7	Sample Chain of Custody.....	5
8	Cord Blood labeling	5
9	Cord Blood Collection for PBMC, Plasma and Serum.....	5
10	Helpful Links	8
11	Limitations.....	8
12	Literature References.....	8

1 Purpose

The purpose of this SOP is to document the procedures for collecting, storing and shipping samples collected from Umbilical Cord Blood.

2 Scope

Users of the ACTG/IMPAACT Laboratory Manual

3 Background

Most protocols undertaken by the AIDS Clinical Trials Group and IMPAACT Network are clinical in nature, with both real time and post-study requirements. Real-time assay results may be used to determine individual patient responses to therapies and determine when changes in protocol steps (i.e. changes in patient management) are warranted. Post study analyses are used to make recommendations for future treatment and management models for patient populations. As such, all specimens should be processed appropriately to ensure the best results for both individual patient management and completion of the collective protocol objectives.

The success of a protocol depends upon the adequate collection, processing, preservation, storage, transport, and retrieval of specimens. Guidelines for sample collection and storage need to anticipate the requirements of future studies that are yet to be designed or technological advances which are in the early stages of development. While this is not always possible, certain basic tenets exist. For example, all specimens should be collected and processed using aseptic techniques and Universal Safety Precautions. This includes the use of sterile tubes, pipette tips and reagents, and a work environment that is designed to prevent contamination of samples and provide adequate safety measures for everyone in the lab.

Placental/umbilical cord blood contains numerous fetal cells that can be studied and may play a role in a variety of diseases. Samples are helpful in immune response and nutritional studies. Placental/umbilical cord blood contains hematopoietic stem and progenitor cells that can substitute for bone marrow in human bone marrow transplants. They can be cryopreserved in the laboratory for later use.

The cord blood will be collected after the infant has delivered and the umbilical cord has been cut – separating the infant from the placenta. The blood that remains in the placenta/umbilical cord is no longer of any use to the infant and is considered biological waste. Therefore there is no risk to mother or baby in the process of collecting cord blood.

4 Authority and Responsibility

- 4.1 The Network Laboratory Directors (or his/her designee) have the authority to establish, review and update this procedure.
- 4.2 The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is responsible for the maintenance and control of SOP documentation.
- 4.3 The Laboratory Director is responsible for the implementation of this LTC SOP or laboratory-specific SOP and for ensuring that all appropriate personnel are trained. A laboratory-specific SOP must:

- 4.3.1 Include, without procedural modification, the portions of the current version of the LTC SOP that are used within the network site-affiliated laboratory;
- 4.3.2 Reference the current version of the LTC SOP.
- 4.4 All technicians are responsible for reading and understanding this SOP prior to performing the procedures described.
- 4.5 The site PI and designees are responsible for understanding and adhering to the patient preparation and specimen collection components.

5 Reagents and Materials

- 5.1 Material for Butterfly collection method
 - 5.1.1 Butterfly needle or 18 gauge needle
 - 5.1.1.1 It is strongly recommended that you use a butterfly needle when collecting the cord blood using the needle and vacutainer tube method
 - 5.1.2 Vacutainers, Dependent on protocol requirements
 - 5.1.2.1 Use EDTA for PBMC/plasma Collection
 - 5.1.2.2 SST or NON red top for serum collection
 - 5.1.2.3 Or as directed by protocol
 - 5.1.3 Sterile gauze swabs 7.5 x 7.5cm
 - 5.1.4 Cleansing wipes or betadine solution
 - 5.1.5 One Pair of sterile scissors
 - 5.1.6 Two surgical clamps
 - 5.1.7 Gloves. Preferably powder free
- 5.2 Umbilical Cord Blood Collection using Umbilicup, additional supplies
 - 5.2.1 MKMI Medical Innovations (www.umbilicup.com) Tel: 818- 501-6564
 - 5.2.2 DeRoyal Surgical Tel: 1-800-251-9864

6 Biosafety

- 6.1 It is essential that universal precautions be taken while working with or collecting biological specimens. Whole blood handled during specimen collection and reconstituted specimens obtained during processing may be hazardous. Appropriate personal protective equipment, including gloves and a lab coat/gown, should be worn at all times, to ensure safe handling of samples. If you should tear a glove, remove the torn one and replace it immediately. If a needle puncture should occur, follow your site/institution policy for handling work-related injuries.

- 6.2 The use of protective equipment (rubber apron, single use gloves, and safety goggles) is required when performing this procedure.

7 Sample Chain of Custody

All sites must have a Standard Operating Procedure (SOP) for Sample Chain of Custody in place before study activation. The Chain of Custody SOP must track when specimens are transferred between clinics, processing units, and laboratories and when results are released to the clinic. Internal movements (within the same laboratory) of specimens and results do not need to be tracked. Laboratories with Laboratory Information Management Systems (LIMS) or the Laboratory Data Management System (LDMS) may be able to track this information electronically. Other laboratories will need to devise a system of log books. These systems must capture the personnel receiving/delivering specimens or results and the time and date of the transfer. Accountability for the samples must be maintained, with requirements for signatures of the involved parties (i.e. each individual who handled the specimen). Specific information that must accompany the specimen includes: the PID, SID, collection time and date, and visit code for each specimen. The site SOP should also detail how the results are returned from the lab to the clinic as well as how problem samples are reported back to the clinic.

8 Cord Blood labeling

- 8.1 All samples collected at a participant visit must be labeled at the time of collection with the PID; visit; collection date and time; and collector's initials. PID and visit numbers must be pre-printed on these labels; however study staff must write the specimen collection date and time on each label. When specimens are tested at the local lab, any additional labeling required for on-site specimen management and chain of custody will be performed in accordance with the site SOP
- 8.2 The LDMS must be used at all sites to track the collection, storage, and shipment of cord blood specimens sent to processing or testing laboratories within NIH-sponsored clinical trials networks (e.g. IMPAACT). Detailed instructions for use of the LDMS are available at: <https://www.fstrf.org/apps/cfmx/apps/ldms/manual/manual.html>
- 8.3 Enter cord blood samples into the LDMS with the primary type=CRD, additive= EDT or NON (or appropriate additive if a different tube type is received) and derivative = CEL, SER or PLA
- 8.3.1 SERUM (CRD/NON or SST/SER)
- 8.3.2 PBMC (CRD/EDT/CEL/DMS)
- 8.3.3 Plasma (CRD/EDT/PLA)
- 8.4 Ensure that each LDMS label contains the protocol (ACTG/IMPAACT) required identifiers, which include but are not limited to the patient ID, visit, sample dates, and draw times.

9 Cord Blood Collection for PBMC, Plasma and Serum

- 9.1 Cord blood collected EX-UTERO should be performed as soon as it is safely possible once the placenta has been delivered and before the natural clotting process begins. (This needs to

be taken into consideration when a physiological delivery of the placenta takes place as the natural clotting process may reduce the amount of cord blood available for collection.)

- 9.2 If feasible, collect the cord blood when delivery takes place in the clinic during the hours when a study nurse is available. However, if it is possible to collect cord blood during off clinic hours, then collect it following your institution's chain of custody procedure
- 9.3 Cord Blood Collection using Butterfly Needle and Vacutainer Tubes:
 - 9.3.1 After the delivery of the infant, double clamp the umbilical cord and cut the umbilical cord as usual.
 - 9.3.2 Apply the first clamp near the placenta.
 - 9.3.3 Apply the second clamp to the cord on the baby side.

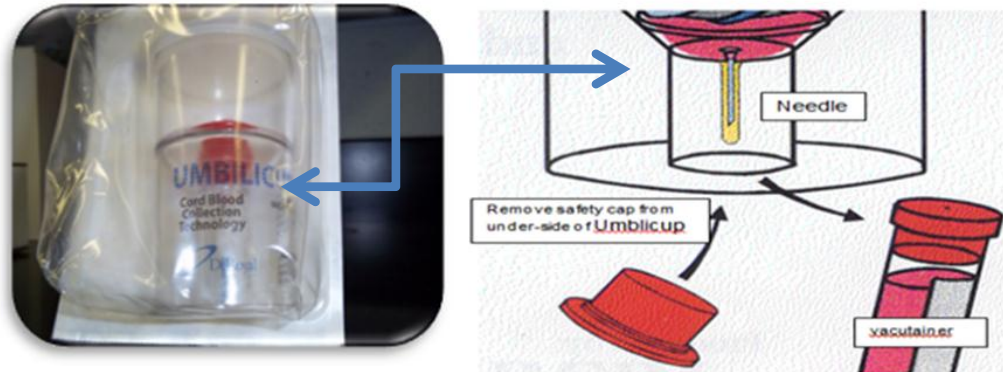


- 9.3.4 Cleanse a 4" - 6" area of the umbilical cord with alcohol followed by betadine to remove maternal blood and contaminants (before the delivery of the placenta, if possible).
- 9.3.5 Using the butterfly needle and vacutainer tubes:



- 9.3.5.1 Collect cord blood in a SST or NON (red top) tube(s) for serum storage.
NOTE: collect serum before EDTA or any other anticoagulant containing tube
- 9.3.5.2 Collect cord blood in EDTA tube(s) for plasma and PBMC storage.
- 9.3.5.3 Mix tube by inverting 8-10 times.
- 9.3.6 Process specimens within one hour of collection.

9.4 Cord Blood Collection using Umbilicup



- 9.4.1 The Umbilicup Umbilical Cord Blood Collection System is packaged sterilely and holds approximately 100mL. It includes at its **bottom a needle**, which is enclosed to prevent needle sticks.
- 9.4.2 Use standard vacutainer-type tubes with rubber caps when collecting the sample with the Umbilicup.
- 9.4.3 Open the package using sterile technique. Remove the Umbilicup from the sterile packaging and place on a sterile field near the mother. **WORK QUICKLY** as blood clots rapidly
- 9.4.4 After the delivery of the infant and placenta, double clamp the umbilical cord and cut the umbilical cord as usual. When placing the clamps on, apply the first clamp near the placenta and apply the second clamp on the baby side.
- 9.4.5 Wipe the umbilical cord with alcohol followed by betadine to remove maternal blood and contaminants (before the delivery of the placenta, if possible).
- 9.4.6 Remove the lid of the Umbilicup; position the Umbilicup under the cut end of the umbilical cord.
- 9.4.7 Slowly release the clamp, allowing as much umbilical cord blood as possible to drip into the Umbilicup. The user may also milk the umbilical cord to obtain a larger volume of blood, as needed.
- 9.4.8 Place the cap on top of the Umbilicup.
- 9.4.9 Using SST tubes
 - 9.4.9.1 Collect cord blood in SST tubes for blood and serum collection.
 - 9.4.9.2 Insert an empty SST or red top tube into the needle sleeve at the bottom of the Umbilicup. Collect blood in the vacutainer tube(s).
 - 9.4.9.3 Place the SST tube in the refrigerator
- 9.4.10 Using EDTA Tubes
 - 9.4.10.1 Collect cord blood in EDTA tube(s) for plasma and PBMC storage

9.4.10.2 Mix EDTA tube by inverting 8-10 times.

9.4.10.3 Keep EDTA tube at room temperature until delivery to the lab

9.4.11 Ensure all samples are labeled with patient's PID and suffix "CRD". All sample labels should contain the time and date of collection as well as the time and date of delivery

9.5 The cord blood can also be collected using your clinic or hospital's collection procedures as long as the safety procedures are followed and contamination of cord blood is avoided.

10 Helpful Links

10.1 HANC website for <http://www.hanc.info/labs/labresources/Pages/informationActgImpaactLabs.aspx> for the following resources:

10.1.1 ACTG-IMPACT Laboratory Manual

10.1.2 Cross-network PBMC Processing SOP

10.2 DAIDS Guidelines for Good Clinical Laboratory Practice Standards: <http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf>

10.3 LDMS website: <http://www.fstrf.org/ldms/index.html>

11 Limitations

11.1 There will be no cord blood collection from women who deliver at home or at a non-research facility

12 Literature References

12.1 1077 BF MOP