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| Standard Operating Procedure Document ID :<br><b>SOP-TR-002</b><br>Version number: 2.0 |  |
| Category: Material Handling and Documentation  | Effective Date :<br><b>01/Jul/2011</b>   |
| <b>COLLECTION AND STORAGE OF CTAD PLASMA</b>   |  |

## 1. SOP DETAILS

| Author :  | Title                                 | Date        |
|---|---------------------------------------|-------------|
| Adriana Aguilar   | Scientific Advisor                    | 07/Feb/2010 |
| Signature:<br> |                                       |             |
| <b>Approval :</b>   |                                       |             |
| Zuanel Diaz   | Manager –<br>Translational<br>Program | 01/Jul/2011 |
| Signature:<br> |                                       |             |

## 2. PURPOSE


The aim of this Standard Operating Procedure is to standardize the collection, processing, handling and storage of CTAD plasma samples.

## 3. APPLICABLE TO

This SOP is to be read and applied by all personnel involved in all Q-CROC projects where CTAD plasma needs to be collected.

## 4. SUPPLIES

- 2 x CTAD tubes (4.5mL) (Store at Room Temperature and Protect from Light)
- 7 x Polypropylene Cryovial Tubes (Containing Barcodes, 2.0mL)
- 7 x Protocol Specific Labels
- Rack for Cryovial Tubes
- Centrifuge
- Pipettor (1000µL)
- Sterile Tips for Pipettor (1000uL)
- Biohazard and Sharps Waste Containers
- 1 x Storage Box

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1 x Label for Storage Box  
-80°C Freezer  
Requisition Form and Pen

## 5. PRECAUTIONS

Gloves must be worn at all times when handling specimens. This includes during removal of the rubber stopper from the blood tubes, centrifugation, pipetting, disposal of contaminated tubes, and cleanup of any spills. Tubes, needles, and pipets must be properly disposed of in biohazard containers, in accordance with institutional requirements. Blood material is considered a biohazard and should be handled using universal precaution according to local Health and Safety rules.

**Note: CTAD tubes should be stored at room temperature and protected from light. Wrap the tube in foil until plasma has been processed.**


## 6. WORKING PROCEDURES

Before the blood draw:

- Enter all information on labels. You will need approximately 7 labels.
- Enter the barcode number of the cryovial tubes on the requisition form (approx 7 cryovials), taking care to place the cryovials tubes in a rack in the order written on the requisition form.

After the blood draw:

- Collect blood in 2 x 4.5 mL CTAD tubes.
- Right after collection, blood tubes need to be inverted 10 times to mix blood with CTAD.
- Record the blood collection time in the requisition form (time should be indicated on the tube by the nurse)
- Blood processing must begin as soon as possible and ideally within 30 minutes of collection from the donor. Samples should be kept at room temperature at all times and **never** stored at 4°C before processing.


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- Place CTAD tubes into a centrifuge; ensure it is balanced, and spin at approximately 1500x g for 15 minutes. CENTRIFUGE MUST BE AT ROOM TEMPERATURE.
- Record the blood processing start time in the requisition form.
- Remove the tubes carefully from the centrifuge to avoid disturbing the cells.
- Remove 500µL aliquots of plasma (top layer) using a pipettor and place the aliquots into the separate cryovial tubes already on the rack. At the end of pipetting the plasma, record the total volume of plasma on the requisition form by adding all the aliquots. Record the color of plasma (yellow, pink, red).
- Wrap the labels around the cryovial tubes.
- IMMEDIATELY bring the cryovial tubes to the -80°C freezer and place them into an appropriately labeled storage box. If samples are to be added to a new box, enter all the information on the label, place it on the box and then place the cryovials on the box. Immediately bring the box to the -80°C freezer.
- Record the time when samples were put at -80°C and the emplacement of the box in the freezer as well as the location of the cryovial tubes in the box.
- Ship the box when completely full as indicated on SOP-TR-005.

Any deviation to this procedure should be carefully recorded on the protocol deviation log.

## 7. REVISION HISTORY

| SOP Document ID | Version # | Effective date | Changed by | Description of changes   |
|-----------------|-----------|----------------|------------|--|
| SOP-TR-002      | 1.0       | 13/Jan/2010    | A.A.       | Initial Version  |
| SOP-TR-002      | 2.0       | 01/Jul/2011    | E.B.       | Format change<br>Content change<br>ID number format change<br>Separation of appendix |
| SOP-TR-002      | 2.0       | 01/Jul/2011    | S.Q.       | Quality control check  |

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## 8. ABBREVIATIONS/DEFINITIONS

| Abbreviation | Description                                 |
|--------------|---|
| CTAD         | Citrate Theophylline Adenosine Dipyridamole |
|              |   |

## 9. APPENDICES

| Appendix ID number | Name   | Description   |
|--------------------|--|---|
| APP-TR-002         | Requisition Form for Collection and Storage of CTAD Plasma | Requisition form used to record data related to collection and storage of CTAD plasma |
| APP-TR-014         | Protocol Deviation Log                                     | Regulatory form used to record protocol deviations                                    |