Standard Operating Procedure Document ID : **SOP-TR-003** **Version number: 2.0**	
Category: Material Handling and Documentation	**Effective Date :** **01/Jul/2011**

COLLECTION AND STORAGE OF k-EDTA PLASMA

1. SOP DETAILS

Author :	**Title**	**Date**
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Approval :		
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Signature: 		

2. PURPOSE

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

3. APPLICABLE TO

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

4. SUPPLIES

2 x k-EDTA tubes (4ml)
7 x Polypropylene Cryovial Tubes (Containing Barcodes, 2.0mL)
7 x Protocol Specific Labels
Rack for Cryovial Tubes
Centrifuge
Pipettor (1000 µL)
Sterile Tips for Pipettor (1000 µL)
Biohazard and Sharps Waste Containers
1 x Storage Box

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 clean up 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 precautions according to local Health and Safety rules.

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 or CRF, 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 mL k-EDTA tubes.
- Right after collection, blood tubes need to be inverted 10 times to mix blood and anti-coagulants.
- 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.
- Place EDTA tubes into a centrifuge, ensure it is balanced, and spin at approximately 1500 x g for 15 minutes at room temperature. CENTRIFUGE MUST BE AT ROOM TEMPERATURE.

- Record the blood processing start time in 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 cryovials.
- 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 in the box. Immediately bring the box to the -80^{o}C freezer.
- Record the time when samples were put at -80°C, 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-003	1.0	13/Jan/2010	A.A	Initial version
SOP-TR-003	2.0	01/Jul/2011	E.B.	Format change, removal date on CRF ID number format change Separation of appendice
SOP-TR-003	2.0	01/Jul/2011	S.Q.	Quality check control

8. ABBREVIATIONS/DEFINITIONS

Abbreviation	Description
EDTA	Ethylene Diamine Tetraacetic Acid

9. APPENDICES

Appendix ID Number	Name	Description
APP-TR-003	Requisition Form for Collection and Storage of k-EDTA Plasma	Requisition form used to record data related to collection and storage of k-EDTA plasma
APP-TR-014	Protocol Deviation Log	Regulatory form used to record protocol deviations