KCMC Biotechnology Laboratory	STANDARD OPERATING PROCEDURE	Effective Date 02-10-2006	SOP-Number FLOW007.01
		Page 1 of 9	02-10-2006

Title: Specimen Accessioning

SOP References: **Supersedes:**

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Reviewed by:	**Review Date**	**Signature**

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Definitions and Abbreviations

EDTA	Ethylene Diamine Tetraacetic Acid
ISAAC	International Studies of AIDS Associated Co-Infections
ID	Identification Number
KCMC	Kilimanjaro Christian Medical Centre
SOP	Standard Operating Procedures
QNS	Quantity Not Sufficient

1. Method Summary

Before the laboratory can accept a sample, certain criteria must be followed to assure the validity of the specimen.
All specimens accepted by the laboratory must be examined to ascertain that they meet the proper criteria for processing and data entry. In addition, correct processing and data entry is extremely important to assure that the results given out are correct. And finally, there must be verification that the results are for the intended patient.

2. Scope

This SOP applies to all staff at the KCMC Biotechnology laboratory who use the FACSCalibur. Only authorized staff may use the FACSCalibur.

3. Safety Precautions

3.1. Follow Standard biosafety Precautions for handling of blood specimens (See Biohazard SOP [SFT.01]).

3.2. Any forms that are sent in contact with the specimens (i.e. wrapped around specimen container with rubber band) should be discarded after the proper information is obtained. They are not to be filed.

4. Sample Verification

4.1. All specimens are to be accompanied by a completely filled sample collection form and tracking form (see appendix 1 and 2 respectively). The specimen should contain the following information:

4.1.1. Patient ID, Date and time of sample collection, study ID and Visit number (time-point in study).

4.2. Forms should be checked to make sure all appropriate information is provided and that it matches the information on the specimen container. Forms should contain the following information:

4.2.1. Patient ID number

4.2.2. Study number (if applicable)

4.2.3. Time-point in study

4.2.4. Clinician requesting for the test

4.2.5. Date of sample collection

4.2.6. Time sample was drawn

4.2.7. The name of the phlebotomist

4.2.8. Name and signature of procuring individual (research nurse or research assistants).

4.2.9. Sample type and assay type requested for.

5. Criteria and procedure for Rejection of Unacceptable Specimens

5.1 Specimens may be rejected for the following reasons:

5.1.1. Quantity not sufficient (QNS).

5.1.2. Clotted specimen

5.1.3 Lack of procurement information as listed on sample collection form (appendix 1).

5.1.4 Hemolysed blood specimen.

5.1.5 Sample more than 24 hours old.

5.1.6 Specimens transported on ice/ice packs.

5.1.7 Incorrectly labeled specimen (not matching the information on sample forms).

5.1.8 Unlabeled specimen

5.1.9 Specimen drawn into tube containing anticoagulant different from protocol specification (i.e EDTA).

5.2. Specimen Rejection Procedure

5.2.1. Unlabeled or mislabeled specimen should be handled as follows:

a. Do not accession.

b. Contact procuring individual. If in doubt about labeling information, the sample should be discarded, documented, and patient rescheduled for another sample to be drawn.

5.2.2 Fill out specimen rejection form (see appendix 3).

5.2.3 Notify appropriate clinician and procuring individual.

5.2.4 File specimen rejection form in specimen rejection file.

6. Computer Data Accession Procedure

6.1. The accession book is the data entry point for all samples. No sample should be processed without being assigned an accession number and a daily number. All information received with a specimen should be logged into the database. The forms should be taken to the data management unit of KCMC. The information should be handled according to the data management unit policy # 1.04 for data entry.

Reference:
N/A

Appendix 1: Sample Collection Form

FORM 1: SAMPLE COLLECTION

Study: _____ Visit: _____

1. Date: _____/_____/_____ 2. Sample ID: _____
dd/ mm /yyyy

3. Age: _____ 4. Date of Birth: _____/_____/_____
dd /mm /yyyy

5. Gender: _____ (m/f)

6. Individual consent obtained: _____

7. If yes, HIV antibody test results: ( ) Negative ( ) Positive

8. Volume of blood sample drawn: _____mL (In EDTA anticoagulant)

9. Date and Time of sample collection: _____:_____
hh : mm

10. Name of personnel who obtained sample: _____

Immunology Laboratory

11. Sample received by: _____

12. Date and Time received: _____/_____/_____. _____:_____
dd/ mm/ yyyy hh : mm

Comments:
_____
_____
_____
___

Appendix 2: Sample Tracking Form

FORM 2: SAMPLE TRACKING

DATE: _____/_____/_____ STUDY: _____

dd / mm / yyyy

SAMPLE ID	NO. OF VIALS	CONFIRM RECEIPT (√)

Form completed by: Name _____ Sign _____

Date and Time samples released: _____/_____/_____. _____:_____

dd / mm /yyyy hh : mm

Name of Research nurse/assistant: _____ Sign: _____

Immunology Laboratory

Sample received by: _____

Date and time received: _____/_____/_____. _____:_____

dd / mm /yyyy hh :mm

Comments: _____

_____

Appendix 3.
Flow Cytometry for CD4 enumeration
Specimen Rejection Form

Date: _____ Patient ID: _____

Sample collected by: _____

Date and Time of collection: ____/___/_____ _____:_____
dd/mm/yyyy hh : mm

Date and time received in the immunology laboratory: ____/_____/____ ____:____
dd /mm/yyyy hh :mm

Sample received by: _____ Sign: _____

Reason for rejection: **(√)** the applicable one

( ) Quantity Not Sufficient (QNS)

( ) Clotted specimen

( ) Lack of, or improper procurement information as listed on the sample collection form (appendix 1)

( ) Hemolyzed blood specimen.

( ) Sample more than 24 hours old.

( ) Specimens transported on ice/ice packs.

( ) Incorrectly labeled specimen (un matching information on specimen and forms).

( ) Unlabeled specimen

( ) Specimen drawn into tube containing anticoagulant different from protocol specification (i.e EDTA).

Sample rejected by: _____ Date: _____

Comments:
_____
_____
_____