KCMC Biotechnology Laboratory	STANDARD OPERATING PROCEDURE	Effective Date: 02-10-2006	SOP-Number FLOW008.01
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Title: **Data Entry, Interpretation, Reporting and Storage**

SOP References: **Supersedes:**

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Approvals/Date:

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QuickTime™ and a TIFF (Uncompressed) decompressor are needed to see this picture.

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Guido Ferrari, M.D.
ISAAC Pathogenesis Program Co-Director

This SOP has been read and understood by:

Name	Date
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Annual Review		
Reviewed by:	**Review Date**	**Signature**

Document History:

Version Number	Reason for Changes	Date
FLOW008.01	Initial	16-08-2006

Definitions and Abbreviations

CD	Cluster Designation
ISAAC	International Studies of AIDS Associated Co-Infections
ID	Identification Number
KCMC	Kilimanjaro Christian Medical Centre
NCCLS	National Committee on Clinical Laboratory Standards
QNS	Quantity Not Sufficient
SOP	Standard Operating Procedures

1. Method Summary

In order to keep accurate records, all patients' identifiers and results will be entered into KCMC Computer Database at the data management Unit. This ensures accurate record keeping and storing of all results. In addition, it allows for easy data retrieval and data reporting.

No sample should be processed without first being entered into the database and subsequently assigned an accession number (See Accessioning, SOP# FLOW007.01). All information received about a specimen must also be logged into the database. This allows laboratory staff to keep track of the work they have done, establish normal values, identify trends, and allows easy access to patients' results for clinicians by the laboratory director.

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. Data Entry

After completion of data analyses, the results are printed out on laboratory and physician reports. Enter the CD4 absolute counts and CD4 percentages into the computer database. In addition, CD4 absolute count and percentage summary results should be entered on a results reporting form. This should be performed by the data management staff following the data entry policy # 1.04.

4. Data Interpretation

4.1. The laboratory director, the lab supervisor or designated person is responsible for the initial reviewing of results.

4.1.1. Patient's results are compared to normal ranges.

4.1.2. Report is checked for clerical errors.

4.1.3. The value of $CD3^{+}CD4^{+}$ + $CD3^{+}CD8^{+}$ is checked, and it should be between 95-105 % of the $CD45^{+}CD3^{+}$.

4.1.4. The accession #, date of report, hospital and hospital #, study ID, dot plots, proper gating, number of gated events should be evaluated.

4.1.5. Out of reference range results are starred (***).

4.1.6. Comments such as 'Delta Checks out of Range' are entered on hard copy and in computer sign out.

4.2. If for any reason the Immunology Laboratory Director questions the results as not valid, the specimen can be re-stained (specimen must not be more than 24 hours old) or, a new specimen may be requested and the values not reported.

4.3. If the Immunology Laboratory Director feels the results are probably valid, even though there is a discrepancy, "Out of Range Value. Please Resubmit if Clinically Indicated." must be printed on report.

4.4 The Immunology Laboratory Director then signs, dates the report, and then sign out in the computer. Only the Laboratory Director is entitled to sign out results in the computer. In the event that a report that has already been sent out needs correction, a new report is issued with "updated report" written on it. The old report is retained in the patient file.

5. Data Reporting

5.1. Report data in terms of cluster designations (CD) with a brief description of cell reactivity and monoclonal antibody used.

5.2 Report % for $CD3^{+}CD4^{+}$ lymphocyte subset.

5.3. Report absolute counts for $CD3^{+}CD4^{+}$ lymphocyte subsets.

6. Comments for Repeat Testing.

6.1. Specimen not labeled or incorrectly labeled

6.2. Low % lymphocytes in gate.

6.3. Specimen clotted.

6.4. Specimen more than 24 hours old.

6.5. Specimen exposed to cold temperatures (on ice/ice packs).

6.6. Specimen hemolyzed.

6.7. Specimen Quantity Not Sufficient (QNS)

6.8. **'**Delta checks out of range. Please resubmit if clinically indicated.'

7. Hard Copy of Results

The hard copy of results is given to the accession area that then sends it to the appropriate clinician, clinic or study.

Results should be analyzed and reported the following day. Turnaround time is 1 day. A requisition form if any should be completed and a copy filed.

8. Data Storage

8.1. The hard copy of results and analysis is filed and kept for 5 years.

8.2. The data in the computer is saved on the network and backed up on CDs, Tapes and kept for 5 years.

9. References

1. NCCLS Proposed Guidelines for Flow Cytometry, 1994

2 College of American Pathologists Guidelines for Flow Cytometry, 2000

Appendices:

Appendix 1: Flow Cytometry Data Report Form

KCMC/DUKE UNIVERSITY COLLABORATION, IMMUNOLOGY LABORATORY, BIOTECHNOLOGY LABORATORY, P.O BOX 2222, MOSHI, TANZANIA.

RESULTS REPORT FORM

Patient ID: _____ Study ID: _____

Date of Sample Receipt: _____

Date of sample Processing: _____

CD4 Absolute Counts: _____ CD4%: _____

Data entered by: _____ Date: _____

Data verified by: _____ Date: _____

Comments: _____
_____
_____

Appendix 2: Flow Cytometry Physician Report

KCMC ISAAC

MultiSET™ Physician Report

Director: Dr. Chris Drakeley
Operator: Moses

Software: MultiSET V1.1.2
Cytometer: (file-based analysis)

Sample Name: Assay Control
Sample ID: CD-Chex Plus
Case Number:
Panel Name: ACTG CD4 PANEL

Date Acquired: 12-Oct-06 14:49:08
Date Analyzed: Mon, Oct 16, 2006
Reference Range Type: BD

Result Name	%/Ratio	Abs Cnt (cells/µL)	Reference Range
T Lymphs % of Lymphs (CD3+/CD45+)	74		55% – 84%
T Lymphs (CD3+) Abs Cnt		1619	690 – 2540
T Suppressor % of Lymphs (CD3+CD8+/CD45+)	24		13% – 41%
T Suppressor Lymphs (CD3+CD8+) Abs Cnt		600	190 – 1140
T Helper % of Lymphs (CD3+CD4+/CD45+)	45		31% – 60%
T Helper Lymphs (CD3+CD4+) Abs Cnt		1106	410 – 1590
CD3+CD4+CD8+ % of Lymphs (CD3+CD4+CD8+/CD45+)	0		
CD3+CD4+CD8+ Abs Cnt		1	

Multi-tube QC

T Helper/Suppressor Ratio: 1.84

Comments:

Laboratory Director: