

**KCMC Biotechnology
Laboratory, Microbiology**

**STANDARD
OPERATING
PROCEDURE**

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17 March 07

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Date
17 March 2007

Title: SPECIMEN RECEIPT AND HANDLING PROCEDURES FOR ISAAC STUDIES

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This SOP has been read and understood by:

Name	Date
Signatures on original copy.	
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Annual Review	
By	Date

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Document History:

Version Number	Reason for Changes	Date
MIC.011.03	Change of title to make inclusive of all ISAAC studies	12 March 2007
	Instructions for documenting chain of custody on original Lab Request for.	
	Removal of Urine Culture and addition of Urine Archive instructions	
	Change of term "Host Genetic Analysis" to "Plasma/Cell Archive" and clarification of aliquoting instructions..	
	Addition of sputum and gastric aspirate samples for 004.	

Copies distributed to:

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PURPOSE

Procedures for the receipt of samples for ISAAC studies, assessing acceptability, rejection criteria, pre and post analysis storage and distribution of samples to other laboratories for testing or archiving (freezing).

PRINCIPLE

All data must be recorded on laboratory request forms and samples assessed for quality and adequate volume for testing. If critical data is missing or a test cannot be performed because of insufficient quantity or unacceptable quality, additional information or samples must be obtained to assure all tests are performed. Samples must be stored according to guidelines prior to analysis to preserve sample integrity and afterwards should additional or repeat testing be required. Non-archived samples must be treated as infectious waste and autoclaved prior to discarding.

SCOPE

This Standard Operating Procedure applies to the receipt and handling of specimens for the ISAAC studies for all microbiology laboratory personnel who have been trained and are competent in the receipt, handling and distribution of specimens for laboratory tests.

STANDARD PRECAUTIONS

Wear gloves when handling patient specimens to protect from exposure to bloodborne pathogens.

SPECIMEN RECEIPT PROCEDURES

Microbiology staff are responsible for receiving, storing and redirecting specimens when appropriate.

1. Check ISAAC laboratory request form for the following information:

- Patient's name
- Patient's KCMC record number
- Study ID numbers
- Patient ID number
- Patient's date of birth and/or age
- Patient's gender
- Ward location
- ISAAC study selected (if appropriate)
- Date and time of collection
- Initials of collector
- Confirm collection column checked and initialed

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2. If any data is missing, complete a DATA/SPECIMEN CLARIFICATION request form and return to ISAAC Study Coordinator. Process specimens that have study numbers so as not to compromise specimen integrity.
3. Inspect all tubes/bottles for proper labeling with Study ID and Collection date (minimal) and initials of collector. Unlabeled specimens are not acceptable for testing. Complete a DATA/SPECIMEN CLARIFICATION to request properly labeled specimens and return form to ISAAC Study Coordinator.
4. Check off all specimens received in the "Confirm Receipt" column and enter initials in the space provided.
5. Determine if sufficient specimen of acceptable quality is available for all tests (see minimal volumes and rejection criteria in Table 1.).
6. Complete a DATA/SPECIMEN CLARIFICATION form if quantity or quality of specimen is inadequate. Describe tests that cannot be performed and request additional sample. Submit form to ISAAC Study Coordinator.
7. Keep all laboratory test request forms for 10 years in a secure, fire-protected space.

DISTRIBUTION OF SAMPLES TO OTHER LABORATORIES FOR TESTING

1. Consult Table 2. for sample destinations.
2. Make a copy of the request form to be sent with specimen.
3. Recheck that there is adequate sample for testing.
4. Place sample in Biohazard specimen bag and seal.
5. Place in closed container bearing a BIOHAZARD label for transport outside the laboratory.
6. Take samples to the appropriate laboratory.
7. Obtain signature of person receiving the specimen on the original Specimen Request form.

SPECIMEN STORAGE/ARCHIVING

1. Consult Table 2. for specimen storage and handling instructions pre and post analysis.
2. Specimens held for testing in the microbiology laboratory or awaiting aliquoting/archiving should be placed in labeled racks at the appropriate temperatures.
3. Refer to Table 3 that lists tests for which aliquots are required for testing or archiving, and archiving and labeling instructions.

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4. The LDMS (Laboratory Data Management System) will be used for organizing freezer placement and labeling samples. Refer to Specimen Management Using Laboratory Data Management System SOP LDMS.001.
5. Records of sample locations will be retained in log book format until LDMS software for archiving is available.

SPECIMEN DISPOSAL

1. Specimens should be retained for the appropriate length of time post analysis. Refer to Table 2 for retention times.
2. Discard specimens regularly into an biohazard waste bag.
3. Autoclave bag for 15 minutes at 121°C.
4. Place bag in waste disposal area for incineration.

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Table 1. MINIMAL VOLUMES/SPECIMEN REJECTION CRITERIA

TEST	SPECIMEN	MINIMAL VOLUME REQUIRED FOR TESTING	REJECTION CRITERIA
All tests	All types	NA	<ul style="list-style-type: none"> Mislabeled (patient name/PID, SIDs on specimen and request form do not match. Unlabeled (no patient information on specimen) Specimen collected in incorrect tube type. Insufficient quantity for testing.
Blood cultures	BacT/ALERT SA, PF, MB MycoFLYTIC	Any volume will be accepted.	<ul style="list-style-type: none"> Cracked or leaking bottle/tube Color change of detection disc on bottom of BacT/ALERT and MycoFLYTIC bottles.
Isolator	Isolator	1 ml	<ul style="list-style-type: none"> < 1 ml
Rapid HIV Tests	EDTA blood	1 ml	<ul style="list-style-type: none"> < 1 ml
Malaria slide	EDTA blood	4 drops	<ul style="list-style-type: none"> Clotted, hemolyzed, hyperlipemic
Molecular diagnostics	EDTA blood	5 ml	<ul style="list-style-type: none"> <5 ml Clotted
CBC	EDTA blood	50 ul	<ul style="list-style-type: none"> Clotted <50 ul >24 hrs at RT
Acute Serology	Clotted Blood	1 ml serum	<ul style="list-style-type: none"> <2 ml Blood
Host genetic analysis	EDTA blood	5 ml	<ul style="list-style-type: none"> <5 ml Clotted
CD4 Count	EDTA blood	1 ml	<ul style="list-style-type: none"> < 1ml Clotted Hemolyzed >24 hrs at RT
HIV RNA Quantitation	EDTA Blood	1 ml plasma	<ul style="list-style-type: none"> <3 ml blood, Clotted Hemolyzed > 6 hrs post collection
Convalescent serology	Clotted Blood	1 ml serum	<ul style="list-style-type: none"> <2 ml Blood
Urine Archive	Urine	2 ml	<ul style="list-style-type: none"> <2 ml
CSF Culture	CSF	0.1 ml	<ul style="list-style-type: none"> <0.1 ml
Respiratory specimens for AFB culture	Sputum Gastric washing	Any amount	<ul style="list-style-type: none"> Gastric washings that have not been neutralized and are >2 hrs post collection.
Cryptococcal AG	CSF	20 ul	<ul style="list-style-type: none"> <20 ul
Cryptococcal AG	Clotted Blood	1 ml serum	<ul style="list-style-type: none"> <2 ml Blood Blood collected in EDTA

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Table 2. SAMPLE DESTINATIONS & HANDLING INSTRUCTIONS

TEST	TUBE	LAB DESTINATION	SPECIMEN HANDLING/ TESTING INSTRUCTIONS	SPECIMEN HANDLING/STORAGE PRE-ANALYSIS	SPECIMEN HANDLING/ STORAGE POST- ANALYSIS
Blood cultures	BacT/ALERT SA, PF, MB Isolator, MycoFLYTIC	BL ^a MICRO	Load SA, PF, MB bottles in BacT/ALERT instrument. Process Isolator specimen for AFB. Incubate MycoFLYTIC bottle 35° C aerobically.	Store BacT/ALERT and MycoFLYTIC bottles at RT prior to loading/ incubation. Store Isolator at RT prior to processing.	Discard negative blood culture bottles Retain positive bottles until analysis is completed.
HIV Rapid Tests	EDTA	BL MICRO	Send for HIV ELISA specimens with discordant Determine/ Capillus results. If patient is <18 mos and HIV Ab+ send plasma for HIV-1 RNA Quantitation and CD4 count. If patient is HIV Ab+ and >18 months send whole blood sample for CD4 count (see handling and storage requirements for HIV RNA and CD4 counts).	Store whole blood at 2-8 °C up to 3 days. If testing delayed >3 days, centrifuge and remove plasma. Store plasma at 2-8 °C up to 3 days; >3 days freeze plasma at -20° C	If no subsequent testing required, retain sample at 2-8 °C for one week. If additional testing is required, centrifuge at 3500 rpm/ 1500xg for 10 min., remove plasma and submit for testing.
Malaria film	EDTA	JMP ^b	Prepare thick and thin smear. Refer to SOP MIC.040 Preparation of Slides for Blood Parasite Examination.	Store specimen at 2-8 °C.	Retain all slides. Store specimen at 2-8 °C for one week.
Molecular diagnostics	EDTA	BL MICROB	Freeze/archive 5 ml whole blood in 1 ml aliquots in 1.5. ml cryovials and freeze at -80° C	NA	NA
Complete blood count	EDTA	BL HEM	Send minimum 1 ml.	Retain at RT up to 6 hours; after 6 hours store at 2-8 °C up to 24 hrs.	Store at 2-8 °C for 2 days.
Acute or convalescent serology	PLAIN	BL MICRO	Centrifuge at 3500 rpm/1500xg for 10 min, remove serum, freeze/archive serum into 2ml cryovials at -80° C.	Specimen may be stored at 2-8 °C up to 7 days.	NA
Plasma/cell archive	EDTA	BL MICRO	Centrifuge at 3500 rpm/1500xg for 10 min, and aliquot plasma and cells into 2 separate 2 ml	Specimen may be stored at 2-8 °C up to 6 hours	NA

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			cryovials and store -80 °C.	prior to freezing.	
CD4 count	EDTA	BL IMMUN	Done on HIV Pos patients only.	Store at RT up to 24 hrs post collection. Test must be performed within that time period.	Test must be performed within 24 hrs. Specimen not suitable >24 hrs post collection.
HIV RNA Quantitation	EDTA	BL MOLEC	Submit sample on all children <18 mos.	Centrifuge blood at 3500 rpm/1500xg for 10 min, remove plasma and store 2 aliquots of 500 ul each at -80 °C.	Store remaining plasma aliquots at -80 °C for 3 months.
Sputum/Gastric specimens for AFB culture	Sterile cup	BL MICRO	None	Refrigerate sample until processing.	Retain digested sample for 2 weeks at 2-8 °C.
Urine archive (002A or B)	Urine cup	BL MICRO	Aliquot 2 ml into 2 ml cryovial and store -80 °C	Refrigerate urine up to 2 days prior to freezing.	NA
CSF Culture	Sterile tube	BL MICRO	Centrifuge at 3500 rpm/ 1500xg for 10 min. (30 min for AFB culture). Remove supernate to separate tube and plant 0.01 of sediment to Blood and Chocolate agars or mycobacteria media.	Store at RT prior to processing.	Store at 2-8 °C for 1 week.
Cryptococcal AG -blood	PLAIN	BL MICRO	Centrifuge at 3500 rpm/ 1500xg for 10 min. Remove serum to separate tube for testing.	Store at 2-8 °C up to 24 hrs. Freeze at -20 °C if testing delayed.	Freeze at -20 °C for 1 week.
Cryptococcal AG -CSF	Sterile tube	BL MICRO	Centrifuge at 3500 rpm/ 1500xg for 10 min and remove supernate to another tube for testing.	Store at 2-8 °C up to 24 hrs. Freeze at -20 °C if testing delayed.	Freeze at -20 °C for 1 week.

^a Biotechnology Lab ^b Joint Malaria Program Lab

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Table 3 Aliquots/Labels for Freezing Samples

TEST	SPECIMEN	MINIMAL VOLUME REQUIRED FOR TESTING	ALIQUOTS	LABELS
Acute Serology	Clotted Blood	1 ml serum	Aliquot as many 1 ml aliquots of serum as possible into 1.5 ml cryotubes.	LDMS
Plasma/cell archive	EDTA blood	2 ml pelleted cells, 2 ml plasma	Aliquot up to 2 ml of pelleted cells and plasma in 2 separate 2 ml cryovials.	LDMS
Convalescent serology	Clotted Blood	1 ml serum	Distribute as many 1 ml aliquots of serum as possible into 1.5 ml cryotubes. Freeze at -80° C	LDMS
Urine Archive	Urine	Tests to be determined.	Distribute up to 5 – 2 ml aliquots into 2 ml cryotubes. Freeze at -80° C	LDMS
CSF Archive	CSF	Tests to be determined.	Distribute as many 1 ml aliquots of remaining CSF supernate as possible into 2 ml cryotubes after sufficient amount has been removed for cryptococcal AG test.	LDMS

REFERENCES-NA

APPENDIX A – Copy of DATA/SPECIMEN CLARIFICATION FORM