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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** |
| **Study Site:**  | **SOPs Number** : LP-302 |
| **Title****SPECIMEN RECEIPT AND HANDLING PROCEDURES**  |
| **Version Number**:  | **Version Date:**  | **Effective date**:  |
| **Approval name Signature Date**  |

**Annual Review**

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| **Review date**  | **Revision Date**  | **Signature** |
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**Document History**

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| **Version number**  | **Reason for change**  | **Date**  |
| 1.0 | Initial release  | 28th March 2015 |
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**Distribution List**

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1. **Introduction**

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.

1. **Objectives**

This standard operating procedure (SOP) describes the steps for the receipt of blood samples for study, assessing acceptability, rejection criteria, pre and post analysis storage and distribution of samples to other laboratories for testing or archiving (freezing).

1. **Scope**

This SOP applies to the receipt and handling of specimens for all laboratory personnel who have been trained and are competent in the receipt, handling and distribution of specimens for laboratory tests.

1. Responsibility

All laboratory personnel who have been trained and are competent in the receipt, handling and distribution of specimens for laboratory tests.

1. **Standard precautions**

Wear gloves when handling participant specimens to protect from exposure to blood borne pathogens.

1. **Specimen receipt procedures**

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

1. Check laboratory request form for the following information:
	1. Visit Date
	2. Participant’s Gender
	3. Screening ID #
	4. Participant ID #
	5. Date and time of specimen collection
	6. Initials and date of specimen collector
	7. Confirm collection column checked and initialled
2. If any data is missing, complete a DATA/SPECIMEN CLARIFICATION request form and return to Site Coordinator. Process specimens that have study numbers so as not to compromise specimen integrity.
3. Inspect all tubes/bottles for proper labelling 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 labelled specimens and return form to Site 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 Site Coordinator.
7. Keep all laboratory test request forms for 10 years in a secure, fire-protected space.
8. **Distribution of samples to other laboratories for testing**
* Consult Table 2. for sample destinations.
* Make a copy of the request form to be sent with specimen.
* Check that there is adequate sample for testing.
* Place sample in Biohazard specimen bag and seal.
* Take samples to the appropriate laboratory.
* Obtain signature of person receiving the specimen on the original specimen request form.

**7. Specimen storage/archiving**

* Consult Table 2. for specimen storage and handling instructions pre and post analysis.
* Specimens held for testing in the laboratory or awaiting aliquoting/archiving should be placed in labelled racks at the appropriate temperatures.
* Refer to Table 3 that lists tests for which aliquots are required for testing or archiving, and archiving and labelling instructions.
* Each site should use their Laboratory Data Management System for organizing freezer placement and labelling samples. This is to ensure that sites storage style are not disorganised.
* Records of sample locations will be retained in log book format.
1. **Specimen disposal**
* Specimens should be retained for the appropriate length of time post analysis. Refer to Table 2 for retention times.
* Discard specimens regularly into an biohazard waste bag.
* Autoclave bag for 15 minutes at 121o C.
* Place bag in waste disposal area for incineration.
* Record Specimen Collection dates.
* Enter the initials of the staff that made the request and date.

**Table 1. MINIMAL VOLUMES/SPECIMEN REJECTION CRITERIA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Test**  | **Specimen** | **Minimal volume required for testing**  | **Rejection criteria**  |
| All tests | All tests | NA | * Mislabelled (Participant and Screening ID #s on specimen blood and request form do not match.
* Unlabelled (No participant information on specimen)
* Specimen collected in incorrect tube type.
* Insufficient quantity for testing.
 |
| HIV test | Blood  | 1ml | * <1ml
 |
| CD4 count | EDTA Blood | 1ml | * < 5ml
* Clotted
* Haemolysed
* >24 hrs post collection
 |
| HIV RNA Quantitation  | EDTA Blood | 1ml plasma | * <5 ml blood,
* Clotted
* Haemolysed
 |
| Creatinine  | Clotted Blood  | 2ml serum  | * <5ml blood
 |
| Hepatitis B surface antigen  | Serum/plasma | 3ml  | * <5ml blood
 |

**Table 2. SAMPLE DESTINATIONS & HANDLING INSTRUCTIONS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **TUBE** | **LAB DESTINATION** | **SPECIMEN HANDLING/ TESTING INSTRUCTIONS**  | **SPECIMEN HANDLING/STORAGE PRE-ANALYSIS**  | **SPECIMEN HANDLING/STORAGE POST-ANALYSIS**  |
| HIV test | EDTA | Haematology | Sent for Rapid double ELISA  | Store whole blood at 2-8 o C up to 3 days. If testing delayed >3 days, centrifuge and remove plasma. Store plasma at 2-8 o C up to 3 days; >3 days freeze plasma at -20o C.  | Store plasma at 2-8 o C up to 3 days; >3 days freeze plasma at -20o C..  |
| CD4 count | EDTA Blood | Haematology | 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 Viral Quantitation  | EDTA Blood | Haematology | Done on HIV Pos patients only. | Centrifuge blood at 3500 rpm/1500xg for 10 min, remove plasma and store 2 aliquots of 500 ul each at -80 o C.  | Store remaining plasma aliquots at -80 o C  |
| Creatinine  | Clotted Blood  | Chemistry  | Clotted sample only | Serum or plasma (creatinine in serum is stable for 24 hours at 2–8ºC) | Archive serum into 2ml cryovials at -80 o C.  |
| Hepatitis B surface antigen | Serum/plasma | Chemistry | Clotted sample only | Centrifuge at 3500 rpm/1500xg for 10 min, remove serum, freeze/archive serum into 2ml cryovials at -80 o C.  | Archive serum into 2ml cryovials at -80 o C.  |

**This SOP has been read and understood by:**

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| --- | --- | --- | --- |
| **Name**  | **Date**  | **Name** | **Date**  |
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