INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY

COLLEGE OF HEALTH SCIENCES

STANDARD OPERATING PROCEDURE

TITLE: **BIOSPECIMEN ACCEPTANCE AND REJECTION CRITERIA**	**PAGE 1 of 8**

SOP #: **IBRH$_3$AU-SOP-BSP-013.4**	Effective Date: **01/09/2018**	Next Rev: **SEPT 2021**

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VALIDATION AND RETIREMENT

	NAME	DATE
Validated by:		
Retired by:		

ACKNOWLEDGEMENT OF READING AND UNDERSTANDING

I have received and understood the training on this SOP. If I have not understood the training I have asked the trainer to retrain me to ensure that I completely understand all the requirements.

	NAME	SIGNATURE	DATE
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Table of Contents

VALIDATION AND RETIREMENT....1

ACKNOWLEDGEMENT OF READING AND UNDERSTANDING....1

1 PURPOSE....3

2 SCOPE....3

3 LIMITATIONS....3

4 RESPONSIBILITIES....3

5 MATERIALS, REAGENTS AND EQUIPMENT....4

6 PROCEDURES....4

7 REVISION HISTORY....8

1. PURPOSE

This document is to serve as a guide for phlebotomists and lab personnel and to establish requirements for biospecimen acceptance and rejection.

2. SCOPE

This protocol documents the requirements for acceptance and rejection of various biospecimens for processing, archival purposes, and testing. These biospecimens include whole blood, plasma and serum.

3. LIMITATIONS

This protocol cannot be used for reception of animal products, human tissues, cultured cells, Bacterial cells, inoculated cells or recombinant agents

4. RESPONSIBILITIES

The SOP applies to all personnel who are responsible for collecting and processing blood.

Personnel	Responsibility/Role
Biorepository Lab manager	1. Ensures that all personnel involved in sample collection and receiving samples are properly trained and instructed in sample acceptance and rejection processes. 2. Ensures that all Study staff comply with the facility policies concerning acceptance and rejection of biospecimen
Lab technologists	1. Knows and follows biospecimen acceptance and rejection guidelines as set forth in this SOP and any additional ones required by the facility.

5 MATERIALS, REAGENTS AND EQUIPMENT

5.1 Personnel Safety:

5.1.1 Standard Precaution must be observed prior to handling all biospecimens. **Note:** This includes; wearing of gloves and lab coats, eye protection (where indicated if splashing is expected), no open-toed shoes, and no food or drink in the laboratory areas.

5.1.2 All other aspects of safety, as taught and documented, must be followed at all times.

5.1.2.1 Hand gloves

5.1.2.2 Lab coat

5.1.2.3 Closed toe shoes

5.1.2.4 Goggles

5.1.2.5 Client requisition forms

5.1.2.6 Shipping manifest

5.1.2.7 Biospecimen rejection log or equivalent

6 PROCEDURES

6.1. Biospecimen and Paperwork Receipt

6.1.1 Each sample received by the laboratory must be labeled and accompanied by a Requisition Form that matches the information on the tube.

6.1.2 Inspect the contents of the carrier for safety (e.g., no spillage or breakage).

6.1.3 Review the Laboratory Requisition Form and the labeling on the sample tube for completeness of all required information and that they match.

6.1.4 Each requisition must be signed by a valid requestor.

6.1.5 Each requisition must include the date and time of collection. If the information is recoded on the tube instead, transfer it to the requisition form for permanent documentation.

6.1.6 Each requisition must specify the test(s) to be performed.

6.1.7 Each requisition must contain at least one identifier corresponding to the sample collection tubes.

6.1.8 If any of the above information is missing, incomplete, or incorrect the requisition cannot be changed by the laboratory.

6.1.9 Inspect the biospecimens for acceptance.

6.1.10 Complete and submit relevant documentation for any discrepancies or problems with shipment.

6.2 Biospecimen Assessment

6.2.1 Determine whether the sample is appropriate for the test(s) requested. The sample must be collected in the proper tube and meet volume requirements for the specific test(s) requested.

6.2.2 Determine the condition of the biospecimen and whether it is suitable for processing and testing. The following are integrity conditions that are commonly used to describe sample quality.

6.2.3 Satisfactory (SAT): Ideal biospecimen that meets all necessary criteria.

6.2.4 Clotted (CLT): Coagulated blood specimen (for whole blood)

6.2.5 Hemolyzed (Hem): The destruction of red blood cells with the release of hemoglobin into the surrounding fluid; this gives the plasma a red tint

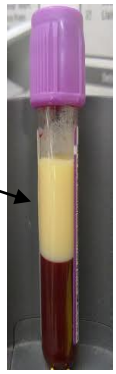
6.3 Precautions for blood sample collection

6.3.1 If using a syringe, avoid excessive pressure on the plunger.

6.3.2 Do not expel blood into a tube through the needle.

6.3.3 Do not shake blood in the container to mix anticoagulants.

6.3.4 Avoid prolonged contact of serum or plasma with blood cells; prompt centrifugation is essential.



6.3.5 Do not refrigerate blood before clotting.

6.3.6 Do not freeze whole blood before centrifuging.

Lipemic (LIP): Turbidity in plasma or serum caused by excess triglycerides. This gives the plasma a "milky" appearance. Precaution:

Avoid drawing blood if patient hasn't eaten within 2 hours of collection

Icteric (ICT): Excess bilirubin in the blood which gives the plasma a yellow-green or "jaundiced" look.

6.3.7 If any of the above conditions are detected document it in the Biospecimen Log. Then consult the SOP of the test(s) requested to determine whether a sample with the indicated condition is acceptable for testing.

6.3.8 Check to see if the volume of sample is sufficient for testing.

6.3.9 If the biospecimen is inappropriate or if the condition of the sample is unacceptable according to the SOP of the requested test(s), reject the sample and request another one. Document who was contacted and the date in the Sample Rejection Log.

6.4 Biospecimen may be rejected if:

6.4.1 The time of biospecimen collection does not meet requirements of the assay to be performed.

6.4.2 Documentation is incomplete or the information documented on the biospecimen label and Requisition Form does not match.

6.4.3 The biospecimen or biospecimen volume is inappropriate or insufficient for the test(s) required.

6.4.4 The biospecimen's condition (integrity) is unacceptable according to the SOP of the test(s) required.

6.4.5 In addition, any of the following reasons may also be grounds to reject a sample for processing.

6.4.6 The tube is not clearly labeled with necessary patient information. If there is any doubt as to whom the biospecimen belongs to, do not process the biospecimen.

6.4.7 If the integrity of the biospecimen has been compromised or contaminated in any way, do not process the biospecimen. The following are several ways that this could occur;

6.4.8 If blood samples from several patients could have been contaminated with other blood.

6.4.9 There was a broken biospecimen container.

6.4.10 There was a delay between collection of biospecimen and arrival in laboratory.

6.5 If the sample is rejected:

6.5.1 Notify the Study Investigator immediately.

6.5.2 Notify the clinical site staff that collected the specimen.

6.5.3 Request another biospecimen.

6.5.4 Note the action taken in the Biospecimen Rejection form and the corresponding Requisition form.

6.5.5 In cases where the Study coordinator allows acceptance of an apparently unacceptable biospecimen, have the Investigator initial the documentation of acceptance

6.5.6 The Study coordinator will determine the need to provide information along with the result report as to the issues surrounding the investigation and the possibility that the biospecimen may have been compromised before testing.

7 REVISION HISTORY

Revision No	Effective Date	Description of Changes Made from Preceding Revision	Approved by/ Date

ANNEX 1: DOCUMENTATION OF SUGGESTED CHANGES TO THIS SOP

CLAUSE	SUGGESTION	BY	DATE