



INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

STANDARD OPERATING PROCEDURE

TITLE: PAXGENE DNA BLOOD SAMPLE COLLECTION

PAGE 1 of 6

SOP #: IBRH₃AU-SOP-BSP-001.1

Effective Date: 09/01/2014

Next Rev: DEC 2015

Prepared by :

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Approved by:

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TITLE: Coordinator

(Signature & Date)

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TITLE: Principal Investigator

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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1. PURPOSE

To describe the procedures required for collection of whole blood using PAXgene blood DNA tube for DNA extraction and purification.

2. SCOPE

The protocol is applicable to all persons seeking to collect whole blood using PAXgene Blood DNA tubes.

3. LIMITATIONS

This protocol is for research purposes only. Not for use in diagnostic purposes. The PAXgene blood DNA tubes should not be used for the collection of other blood samples.

4. RESPONSIBILITIES

PI/Scientific director	<ol style="list-style-type: none"> 1. Determine if the procedures outlined in this SOP for blood collection using PAXgene DNA Tubes are appropriate for sample collection supplies, downstream assays and logistics. 2. Revise this SOP and inform the Study Coordinators/Phlebotomists of any revisions of the protocol.
Phlebotomist/Study Coordinator	<ol style="list-style-type: none"> 1. Ensures he/she has read, understands and follows the SOP while collecting blood from clients using PAXgene DNA tubes. 2. Conducts and assists with blood collection. 3. Records and documents outcomes. 4. Record and notify the Supervisor/Investigator of any deviations from this procedure, which are not accounted for in study specific procedures.



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5. SOP SPECIFIC NEEDS AND REQUIREMENTS

5.1 SOP Specific Personnel Requirements

- 5.1.1 All personnel that collect blood samples must be trained in procedures to handle biological specimen.
- 5.1.2 All personnel that collect blood samples must have read and understood “Guidelines for Phlebotomy”.

5.2 SOP Specific Equipment and Supplies

- 5.2.1 Hand gloves.
- 5.2.2 Laboratory coat
- 5.2.3 Closed toe shoes.
- 5.2.4 PAXgene Blood DNA tube (8.5ml)
- 5.2.5 Vacutainer blood collection set
- 5.2.6 Single use holder
- 5.2.7 Tourniquet
- 5.2.8 Antiseptic (E.g. alcohol swab)
- 5.2.9 Bandage
- 5.2.10 Appropriate labels

6. PROCEDURE

6.1 Pre Sample Collection

- 6.1.1 Ensure that the PAXgene blood DNA tube is at room temperature (18°C to 25°C) prior to use and properly labeled with patient’s identification.
- 6.1.2 The PAXgene blood DNA tube should be drawn after collection of EDTA blood and Plain tube blood.
- 6.1.3 Protective clothing including hand gloves must be worn during sample collection and specimen handling.
- 6.1.4 Label the PAXgene blood DNA tube with appropriate patient identification information.



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6.2 Venipuncture

- 6.2.1 Using a vacutainer blood collection set, collect blood into a labeled PAXgene blood DNA tube, according to recommended standard procedures for venipuncture.

6.3 Blood Collection

- 6.3.1 Hold the PAXgene blood DNA tube vertically, below the blood donor's arm, during blood collection.
- 6.3.2 Allow at least 10 seconds for a complete blood draw to take place. Ensure that the blood has stopped flowing into the tube before removing the tube from the holder.

6.4 Post Blood Collection

- 6.4.1 Dispose of needle in a sharps container. Do not recap needle.
- 6.4.2 Gently invert the PAXgene blood DNA tube 8 to 10 times.
- 6.4.3 PAXgene Blood DNA Tube can be stored upright at room temperature (18°C-25°C) for up to 14 days, at 4°C for up to 28 days, or 3 months at -20°C or long-term at -70°C.
- 6.4.4 Transport all samples at room temperature to the lab for storage at -80°C.
- 6.4.5 If the samples can't be transported the same day store at -20°C until when transferred to the lab for storage under -80°C.



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7. REFERENCES

PAXgene blood DNA tubes kit insert.

8. 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