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AMBITION-*cm*
AMBIsome Therapy Induction OptimizatioN

Laboratory Work Practice Document: 9
PAXgene Specimen Collection and Storage

Title of study	High Dose AMBISOME© on a Fluconazole Backbone for Cryptococcal Meningitis Induction Therapy in sub-Saharan Africa: A Phase III Randomized Controlled Non-inferiority Trial		
Acronym	Ambition-cm – AMBIsome Therapy Induction OptimizatioN		
ISRCTN No.:	ISRCTN72509687		
WPD Current version	Version 1.0 26/06/2019		
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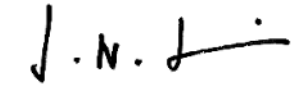
Approved by	Joseph Jarvis CI		28/06/2019

Revision History:		
Version Number	Effective Date	Reason for Change
1.0	28/06/2019	First version

Laboratory Working Practice Document 9: PAXgene Specimen Collection and Storage

Purpose

This document describes the process to collect and store CSF and blood samples in PAXgene tubes. These samples will be analysed at the London School of Hygiene and Tropical Medicine.

References

Ambition Trial Protocol

http://www.bdbiosciences.com/us/applications/blood-collection/cell-biomarker-preservation/paxgenereg-blood-rna-tube/p/762165

Materials

- Lab WPD 2 – Sample Processing and Storage

General Principles

- It is important to follow the guidance below to ensure that the correct quantities of CSF/blood are collected and that the samples are stored correctly.
- Too much or too little sample could lead to incorrect results or poor product performance
- Store the unused PAXgene tubes at 18-25°C prior to use
- As close to exactly 2.5mL of blood and CSF are required from participants on D1 only
- PAXgene tubes can be filled at the bedside
- Please note that each cylindrical PAXgene tube is 100mm long with a 16mm diameter

Section A1 – Blood collection

1. Take blood as per standard procedure
2. If you are withdrawing blood using a needle and syringe, ensure you have at least 2.5mL in your syringe before transferring to the PAXgene tube
3. If you are using a closed blood collection set (e.g. vacutainer) be aware that the PAXgene tube cannot be the first bottle that you use: there is an exact requirement of 2.5mL of blood and if the PAXgene tube is

the first bottle you connect to the system the presence of air in tubing will lead to a reduced quantity of blood in the PAXgene tube.

4. Immediately after drawing blood, gently invert the PAXgene tube 8-10 times.

Section A2– CSF collection

1. Obtain CSF as per standard procedure.
2. Collect CSF in a tube with markings that allow you to identify 2.5mL of CSF.
3. Open the lid of the PAXgene tube, insert the CSF, and close firmly.
4. Immediately after adding the CSF, gently invert the PAXgene tube 8-10 times.

Section B – Storage

1. Immediately after collecting specimens, store the PAXgene tube at 18-25°C for a minimum of 2 hours and a maximum of 72 hours.
2. Samples do not require any processing.
3. The PAXgene tubes can then be stored at -20°C or below.
4. If you would prefer to store at -80°C then it will be necessary to first store at -20°C for at least 24 hours before transferring to the deep freeze.
5. When storing in the freezer the preference is to store on a wire rack: **do not freeze tubes upright in a Styrofoam tray as this may cause the tubes to crack.**
6. If you cannot store on a wire rack then keep the tubes in a freezer bag and store them in a safe, secure position in the freezer.

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Training

Each staff member receives or has direct access to applicable Working Practice Documents (WPDs).

Each staff member reviews the applicable WPDs once a year.

All WPD training is documented and tracked in the training log located in the Investigator Site File (ISF)

New staff is trained on applicable WPDs within 30 days of employment and all WPDs within 90 days of employment.

Staff members whose duties fall within this WPD scope are retrained within 14 days of the approval of each WPD revision.

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Staff signatures: (signing below indicates that you have read this SOP and understand the material contained in it)

Date	Name (Please print)	Signature