



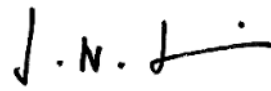


Laboratory Working Practice Document: 1 Laboratory Equipment

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		
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Revision History:		
Version Number	Effective Date	Reason for Change
1.0		First version

Laboratory Working Practice Document 1: Laboratory Equipment

Purpose

This document describes the equipment required in the laboratory for processing CSF samples from trial patients

References

AMBITION Trial Protocol

Laboratory equipment required

- Class I/II biosafety cabinet
- Vortex
- Incubator
- 2-8°C Fridge
- -80°C Freezer
- Fridge thermometer
- Freezer thermometer
- Pipette 100µl
- Pipette 1000µl
- Pipette tips 100µl
- Pipette tips 1000µl
- Racks for test tubes
- QCC Screw capped test tubes/Microcentrifuge tubes
- Sabouraud dextrose agar* (Dextrose powder, peptone and agar powder)
- Chloramphenicol
- Permanent markers
- Petri dishes
- Parafilm
- Gloves
- India Ink*
- CrAg test
- Cryovials (freezer tubes)
- Cryovial boxes
- Sterile Inoculating loops
- Counting chamber/hemocytometer
- Microbank storage beads
- Distilled water
- Centrifuge
- * For India Ink preparation and observations : slide & cover slips
- Biohazard waste cans
- Sharp disposal/container

Lab books x2 - day to day record/documentation of LPs etc.

Waterproof pens: Fat nib (blue and black) and fine nib (black)

Stock check

A weekly stock check must be performed and remaining quantities of essential equipment recorded.

Inform study doctor and trial manager when less than two months' supply of any material is available, to allow adequate time for replacements to be shipped if required.

Laboratory Working Practice Document 1: Laboratory Equipment

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.

