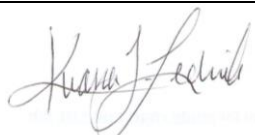


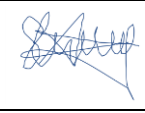
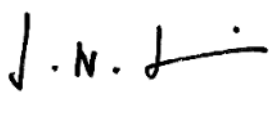


Laboratory Work Practice Document: 4 Cryptococcal Antigen Lateral Flow Assay

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 02/08/2017		
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Approved by	Joseph Jarvis CI		02/08/2017

Revision History:

Version Number	Effective Date	Reason for Change
1.0		First version

Laboratory Working Practice Document 4: Cryptococcal Antigen Lateral Flow Assay



Purpose

This document describes the standard operating procedure (SOP) for the Immy CrAg lateral flow assay

References

CrAg Lateral Flow Assay package insert

Appendices

CrAg Lateral Flow Assay package insert

The CrAg Lateral Flow Assay is an immunochromatographic test system for the detection of the capsular polysaccharide antigens of *Cryptococcus* species complex (*Cryptococcus neoformans* and *Cryptococcus gattii*) in serum, plasma, and cerebral spinal fluid (CSF).

MATERIALS

1. LF Specimen Diluent (2.5 mL): Glycine-buffered saline containing blocking agents and a preservative
2. LF Titration Diluent (6.0 mL): Glycine-buffered saline containing a preservative
3. CrAg LF Test Strips (50 strips in desiccant vial)
4. CrAg Positive Control (1 mL): Glycine-buffered saline spiked with cryptococcal antigen reference strain

STORAGE

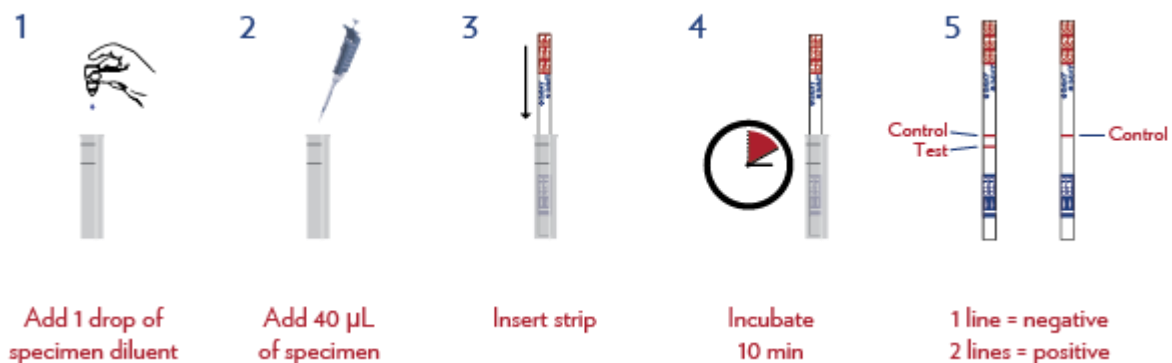
The entire kit should be at room temperature (22-25 °C) before and during use.

Laboratory Working Practice Document 4: Cryptococcal Antigen Lateral Flow Assay

PROCEDURE

1. Write down the ID, number or REF sample on each micro-centrifuge of the corresponding sample.
1. Add 1 drop of LF Specimen Diluent (REF GLF025) to an appropriate reservoir (disposable micro-centrifuge tube, test tubes, or micro-titer plate, etc.).
2. Add 40 μL of specimen to the container and mix.
3. Submerge the white end of a Cryptococcal Antigen Lateral Flow Test Strip into the specimen.
4. Wait 10 minutes, At room temperature (on the bench).
5. Read and record the results. The presence of two lines (test and control), regardless of the intensity of the test line, indicates a positive result.

A single control line indicates a negative result. If the control line does not appear, the results are invalid and the test should be repeated.



The assay has been validated for serum, plasma, and CSF only.

For more information, go to:

- <https://vimeo.com/53970336>
- <https://vimeo.com/54390554>

Laboratory Working Practice Document 4: Cryptococcal Antigen Lateral Flow Assay



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.

Laboratory Working Practice Document 4: Cryptococcal Antigen Lateral Flow Assay

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

Date	Name (Please print)	Signature