Diagnostic Accuracy of the Novel FujiLAM II Assay to Detect Tuberculosis with Advanced HIV Disease

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BACKGROUND

- An urgent need exists for point-of-care diagnostics to detect tuberculosis (TB) among people with advanced HIV disease.
- The Fujifilm SILVAMP TB LAM (FujiLAM II) is a novel point-of-care assay that detects mycobacterial lipoarabinomannan (LAM) antigen in the urine.
- We present a validation of the FujiLAM II assay on prospectively collected urine samples from outpatient adults with advanced HIV disease in Uganda.

METHODS

- We performed a prospective diagnostic accuracy study of the FujiLAM II assay among outpatients with advanced HIV disease at 16 clinics Uganda.
- We determined diagnostic performance for the FujiLAM II test against the cases of confirmed TB (Xpert or mycobacterial culture positive) versus cases without TB.

Subgroups of interest:

- CD4<100 cells/µL
- CD4100-200 cells/µL
- CRP <5 mg/L
- CRP≥5 mg/L
- ART-naive
- ART-experienced



FujiLAM II Assay

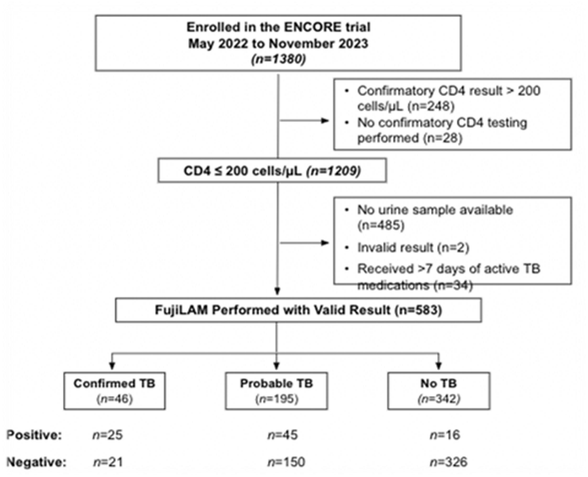


Figure 1. Flow diagram showing participants who had FujiLAM II test performed, and FujiLAM II results according to TB status.

RESULTS

FujiLAM II is a point-of-care, non-sputum-based TB diagnostic with moderate sensitivity (54%) and high specificity (95%) in outpatients with advanced HIV disease. Sensitivity increased to 69% in participants with CD4 <100 cells/µL.

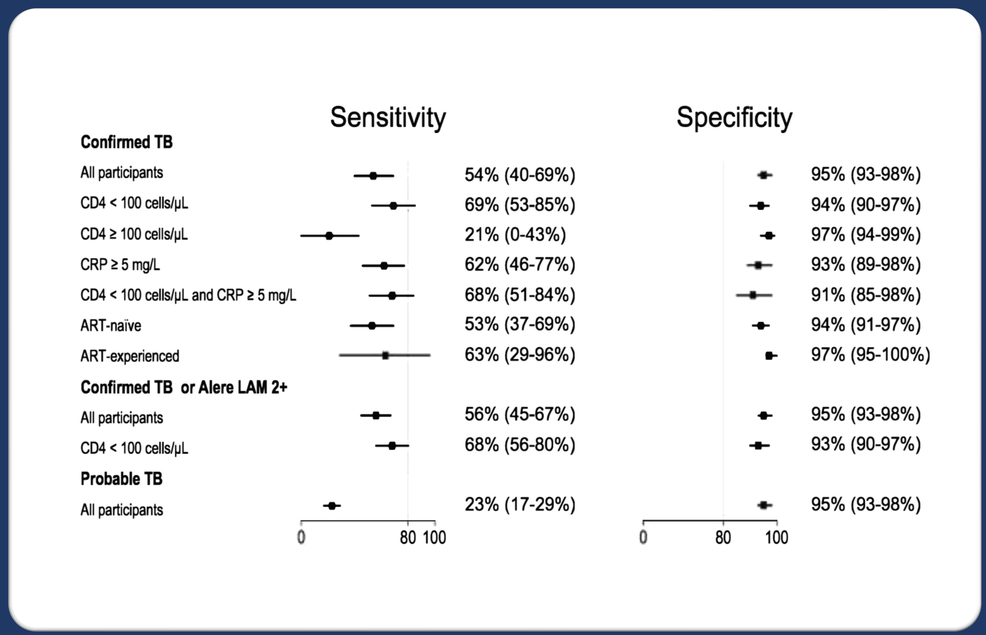


Figure 2. Forest plot highlighting sensitivity and specificity of FujiLAM II

Table 1a FujiLAM II performance in Detecting Participants with Confirmed TB against No TB.

	Confirmed TB	No TB	Total
FujiLAM II positive	25	16	41
FujiLAM II negative	21	326	347
Total	46	342	388

Table 1b FujiLAM II performance in Detecting Participants with Confirmed TB against No TB, among Participants with CD4 cell count < 100 cells/µL

	Confirmed TB	No TB	Total
FujiLAM II positive	22	10	32
FujiLAM II negative	10	145	155
Total	32	155	187

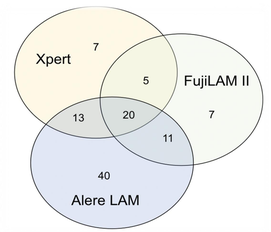


Figure 3. Venn diagram of FujiLAM II, Xpert and Alere LAM test positivity among the 103 participants with all three tests performed and at least one test positive

CONCLUSIONS

- FujiLAM II is a point-of-care, non-sputum-based TB diagnostic with moderate sensitivity and high specificity in outpatients with advanced HIV disease.
- Urine-based TB diagnostics with improved sensitivity are critically needed to reduce mortality and improve early diagnosis among people with advanced HIV disease.

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