

# Use of LAM test for tuberculosis diagnosis

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## Background

Tuberculosis (TB) is the major killer in HIV-positive patients, but remains difficult to diagnose. The lipoarabinomannan assay (LAM) is a urine-based point-of-care test that has shown utility in immunosuppressed HIV-positive patients. Current international guidelines recommend LAM in ambulatory or hospitalized patients with TB symptoms and, CD4<100 cells/ $\mu$ L or seriously ill. We aimed to assess the diagnostic value of LAM in a broader group of patients.

## Methods

A prospective observational study conducted in 6 health facilities in Malawi and Mozambique included 4 groups of HIV-positive patients. All patients had a clinical exam and LAM, chest X-ray, sputum microscopy, and Xpert MTB/RIF assay (Xpert) requested. Culture in sputum was done for a subset of patients. The diagnostic yield was defined as the proportion of patients with a positive assay result among those with laboratory-confirmed TB.

## Results

Among 456 ambulatory patients with TB symptoms and CD4<200 cells/ $\mu$ L (group 1), LAM results were available in 99.6%, compared to 77.0% with Xpert results. LAM could diagnose 82.4% of the patients with laboratory-confirmed TB (Table). Among 485 ambulatory patients with TB symptoms irrespective of their CD4 (group 2), LAM could diagnose 77.9% of the patients with TB. Of the 360 HIV-positive ambulatory patients with CD4<100 cells/ $\mu$ L irrespective of their symptoms (group 3), 11.9% (43/360) were LAM-positive overall, and 6.6% (13/198) among those with no TB symptoms. Among 387 hospitalized patients irrespective of their symptoms and CD4 count (group 4), 25.8% (100/387) were LAM-positive overall, and 19.4% (26/134) among those categorized as “no TB suspects”.

## Conclusion

Expanded use of LAM would be useful in HIV-positive ambulatory patients with TB symptoms and CD4<200 cells/ $\mu$ L, in hospitalized patients regardless of symptoms and, possibly in symptomatic patients with no CD4 result. In ambulatory patients with very low CD4 count coming for initial or regular HIV-consultation, systematic LAM along with symptom screening may also have value for identifying TB.

**Table: Tuberculosis diagnostic tests availability and diagnostic yield in HIV-positive patients**

	Ambulatory patients with symptoms and CD4<200 cells/ $\mu$ L		Ambulatory patients with symptoms irrespective of CD4		Hospitalized patients irrespective of symptoms and CD4	
	Result available N=456 n (%)	Diagnostic yield N=205 n (%)	Result available N=485 n (%)	Diagnostic yield N=104 n (%)	Result available N=387 n (%)	Diagnostic yield N=120 n (%)
LAM	454 (99.6)	169 (82.4)	480 (99.0)	81 (77.9)	384 (99.0)	101 (84.2)
Microscopy	383 (84.0)	69 (33.7)	425 (87.6)	45 (43.3)	243 (62.8)	32 (26.7)
Xpert	351 (77.0)	84 (41.0)	312 (64.3)	44 (42.3)	235 (60.7)	33 (27.5)

LAM would be useful in a broader population than in the one currently recommended, and can be expanded for use in HIV-positive ambulatory symptomatic patients less severely immunocompromised and in HIV-positive hospitalized patients irrespective of their symptoms.