

# Diagnostic performance and feasibility of FujiLAM to detect tuberculosis

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## Background

The novel point-of-care urine-based FujiLAM test is promising for diagnosis of tuberculosis. We assessed the diagnostic yield of FujiLAM in HIV patients and the feasibility of using the test.

## Methods

We conducted a prospective diagnostic study and a mixed-methods feasibility and acceptability study in 4 countries: Uganda, Kenya, Mozambique and South Africa. The diagnostic study included 2 groups of ambulatory HIV-positive adults: 1) with TB symptoms, 2) with advanced HIV disease and no TB symptoms. Patients received FujiLAM and AlereLAM, Xpert MTB/RIF, culture and chest X-ray. The feasibility study included test users, key informants and patients who participated through standard questionnaires, individual interviews and group discussions.

## Results

We included 1117 patients in the diagnostic study: 712 with TB symptoms (Group 1) and 405 with advanced HIV disease and no TB symptoms (Group 2). TB was confirmed in 9.2% (63/685) and 4.1% (16/395) in Group 1 and 2, respectively. FujiLAM diagnostic yield among patients with confirmed TB was 63.2% and 43.8% in Group 1 and 2, respectively. FujiLAM diagnostic yield by CD4 count was: 75.0% in CD4<200, 77.8% in CD4 200-349, 31.3% in CD4≥350 (Group 1) and 46.7% in CD4<200 (Group 2).

Most of the test users (including lay health workers) found FujiLAM easy to perform. The main concern was the multiple timed steps involved. Invalid results were obtained if test cartridges were dropped or performed on blood stained or cloudy urine. Most patients viewed urine sampling positively and easier than sputum provision.

## Conclusions

FujiLAM detects TB in a high proportion of the HIV patients with confirmed TB who have symptoms of TB and low CD4 counts, and in a considerable proportion of those asymptomatic. The test is easy to perform at point-of-care. Urine sampling is well accepted by patients. These results encourage the future use of the FujiLAM assay.

The novel urine-based FujiLAM is a useful and easy to use point-of-care test for TB diagnosis in HIV-positive patients. Urine sampling is well accepted.