

A RAPID TB TEST FOR PEOPLE LIVING WITH HIV

TB LAM can help close the deadly TB testing gap

INTRODUCTION

Médecins Sans Frontières (MSF) has been treating tuberculosis (TB) for more than 30 years and HIV for nearly 20. Our teams currently support treatment for more than 250,000 people living with HIV (PLHIV) in 19 countries, primarily in sub-Saharan Africa. We have many projects in these countries to address TB/HIV co-infection.

This technical brief analyses gaps in the diagnosis of TB for people living with HIV, describes the critical role TB LAM testing can play in saving lives, and provides recommendations for governments to implement and rapidly scale up access to testing.

KEY FACTS

- TB is the leading cause of death among people living with HIV; TB kills 1 in 3 HIV patients and caused 251,000 deaths among people living with HIV in 2018.¹
- Only five countries have met the target to reduce TB deaths among people living with HIV by 75% before the 2020 deadline but a majority of the countries are not on track to achieving the 2020 target according to UNAIDS.²
- Diagnosing TB in people living with HIV is difficult for many reasons, and 44% of all people with HIV-associated TB did not receive care in 2018.³
- Although 62% of people living with HIV receive ART,⁴ high rates of AIDS and advanced HIV disease* continue to be a challenge – affecting not only ART-naïve individuals but also those who have previously been on ART and who might be experiencing treatment failure or interruption of treatment.
- A rapid, true point-of-care urine-based TB test (Determine TB LAM Ag) is available for US\$3.50 per test. TB LAM can quickly diagnose TB in people with AIDS/advanced HIV disease, including those who cannot produce sputum. TB LAM is recommended by the World Health Organization (WHO) to aid in the diagnosis of TB in all people living with HIV and for both inpatients and outpatients.^{5,6}
- TB LAM has been shown to save lives given its ability to quickly diagnose TB and facilitate timely treatment.^{7,8}
- Studies by MSF and others demonstrate the benefits of TB LAM testing for three specific groups of people living with HIV: (1) hospitalised patients, (2) ambulatory patients who are severely ill or have a body mass index (BMI)[†] below 17 and (3) ambulatory patients with a CD4 cell count of <200 cells/mm.^{1,8}
- A novel urine-based LAM test has been developed by FujiFilm (SILVAMP TB LAM test), showing higher sensitivity^{9,10} than the Determine TB LAM test and detecting TB in more HIV patients who have died.¹¹
- Although TB LAM is proven to save lives by enabling earlier treatment initiation and is also shown to be cost effective when added to the diagnostic algorithms in HIV-positive patients,¹² adoption and uptake of this inexpensive test have been surprisingly slow.¹³



* Advanced HIV disease is defined as CD4 cell count <200 cells/mm³ or WHO stage 3 or 4 event. All children younger than five years old with HIV are considered as having advanced HIV disease.

[†] BMI is defined as the body mass divided by the square of the body height and is universally expressed in units of kg/m², resulting from mass in kilograms and height in metres.

THE TB DIAGNOSTIC GAP IN HIV-ASSOCIATED TB

TB is the number one infectious disease killer, claiming 1.5 million lives in 2018 alone.¹ It is also an opportunistic disease, presenting increased risk for people who are immuno-compromised. People living with HIV are 17 to 23 times more likely to develop TB; over 862,000 people living with HIV developed TB in 2018.³

TB is the leading infectious disease killer among people living with HIV. Approximately 50% of tuberculosis cases among people living with HIV were not diagnosed or treated in 2018, resulting in 251,000 deaths – equivalent to approximately one death for every three people living with HIV who developed TB that year.³

Today, 30% to 40% of people worldwide who test positive for HIV and start ART do so with an alarmingly low CD4 count (below 200 cells/mm³) – an indicator of serious immune failure – and are more at risk of developing a deadly opportunistic infection, such as TB.¹⁴

In its guidance for 2020 Country Operational Plans (COPs), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) states: "Delays in TB diagnostic workup and therefore TB treatment and ART initiation result in significant morbidity and mortality; countries should make every effort to expedite the diagnostic process."¹⁵

It is difficult to diagnose TB in people with advanced HIV disease or who are severely ill because (1) they may be unable to produce sputum, (2) sputum can be of poor quality with a very low number of bacteria, or (3) the person may suffer from extra-pulmonary TB (TB infection outside of the lungs). In such instances, sputum-based tests are rendered sub-optimal.^{5,6} Thus, there is a need for simple and accurate tests that can be performed using non-sputum samples. Furthermore, due to the poor health of people with AIDS/advanced HIV disease, faster diagnosis at the point of care, including primary health care facilities, can help save lives by enabling earlier TB treatment initiation.

TB LAM CAN REDUCE TB DEATHS AMONG PEOPLE LIVING WITH HIV

Determine TB LAM Ag (TB LAM) is a urine-based rapid test that allows rapid diagnosis of TB in people living with HIV. TB LAM is specifically recommended for diagnosing TB in those most at risk of death – i.e. people living with HIV with low CD4 counts, or people who are seriously ill or unable to produce sputum.¹⁶ WHO recommended the use of the Alere Determine TB LAM Ag test* in 2015⁵ and updated its policy in 2019,⁶ and it is the only WHO-endorsed point-of-care TB diagnostic test to date. WHO strongly recommends using TB LAM for all HIV-positive inpatients who have signs and symptoms of TB or with advanced HIV disease or seriously ill or have CD4 <200 cells/mm³. For outpatient settings, WHO suggests using TB LAM for PLHIV who have signs and symptoms of TB or seriously ill or have CD4 <100 cells/mm³. TB LAM is estimated

WHAT IS LIPOARABINOMANNAN (LAM)?

LAM is a molecule that is produced by the TB bacteria and makes up part of the outer cell wall of the TB bacteria. Many people with advanced HIV disease have disseminated TB, including TB in their kidneys (renal TB). In these patients, LAM secreted by the TB bacteria circulates in the bloodstream and can be filtered by the kidney, leading to its release in the urine.

to have a pooled sensitivity of 54% and a pooled specificity† of 88% in HIV-positive patients with a CD4 count ≤100 cells/mm³ in inpatient and outpatient settings.¹⁷

Use of TB LAM should be expanded to more people and more facilities

MSF operational research demonstrates the benefits of using TB LAM for people living with HIV with CD4 counts <200 cells/mm³ treated in ambulatory care settings.^{8,18,19} An MSF prospective cohort study included 474 patients living with HIV, of whom 70% had CD4 count <200 cells/mm³, 23% could not produce sputum, 44% were severely ill and 60% had initiated ART. The study showed that of 156 patients with confirmed TB, 65% were LAM-positive. Of those classified as not having TB, 84% were LAM negative. Including LAM increased the diagnostic yield of the algorithms by:

- 37% over clinical signs and X-ray;
- 20% over clinical signs and microscopy;
- 13% over using clinical signs and GeneXpert MTB/RIF rapid molecular testing (Xpert).¹⁹

In a randomised controlled trial conducted in two hospitals in Malawi and South Africa, LAM rapidly diagnosed TB in a high proportion of ambulatory HIV-positive patients with symptoms and CD4 count <200 cells/mm³ and in ambulatory patients who were either severely ill, with CD4 count <200 cells/mm³ or with BMI <17,⁸ some of whom would be missed when relying on conventional sputum-based diagnostic tools.

LAM-positive patients had an increased risk of mortality at two months. A prospective observational study by MSF with 456 HIV-positive people in six health facilities in Malawi and Mozambique showed that 50% (103/205) of individuals with laboratory-confirmed TB were diagnosed only through TB LAM.¹⁹ The same study showed that using LAM in addition to other diagnostic tools (smear and Xpert) increased the proportion of people diagnosed with TB by:

- 38% when added to a diagnostic algorithm including clinical exam, chest X-ray and microscopy;
- 35% when added to an algorithm including clinical exam, chest X-ray, and Xpert.

Given the benefits, there is an urgent need to scale up TB LAM and expand testing under these broader criteria in hospitals as well as peripheral and primary health care facilities.

* Alere Inc., USA was the previous producer of the test, but Abbott has since acquired Alere

† Sensitivity is the proportion of people with a disease that are correctly identified by a diagnostic tool as having the condition. Specificity is the proportion of people without a disease that are correctly identified by a diagnostic tool as not having the condition.

TB LAM should be used for all inpatients living with HIV/AIDS

In a randomised controlled trial conducted by Gupta-Wright and colleagues in two hospitals in Malawi and South Africa, TB LAM was found to be effective in screening all TB asymptomatic HIV-positive hospitalised patients and was also shown to help reduce mortality rates, through faster diagnosis, in hospitalised people living with HIV.

At 56 days, mortality among patients in the intervention group of the study was lower (18%) than the standard-of-care group (21%), who were not tested using TB LAM.⁸

In an MSF study in Kenya, TB LAM was shown to allow same day treatment initiation in patients at higher risk of death and in those unable to produce sputum.²⁰ TB LAM is the only TB test proven to reduce mortality among TB symptomatic inpatients diagnosed and immediately initiated onto treatment.^{21,22}

TB LAM is not meant to replace Xpert but can assist in the diagnosis of TB in people living with HIV. WHO recommends that every TB LAM test be followed up with Xpert. TB LAM was found to increase the yield of Xpert, especially in people living with HIV who cannot produce sputum, as indicated above.²³

TB LAM is affordable and reduces the time to treatment initiation

In addition to its potential to help save lives, TB LAM is rapid*, affordable (just US\$3.50 per test), easy to use after minimal training and requires no instrumentation or electricity.²⁴

A study conducted in a South African district hospital showed no difference in diagnostic accuracy of TB LAM between point-of-care testing versus laboratory testing in emergency care centres in high TB burden settings. 1,388 samples (median 3 samples/participant) were sent for TB microbiology tests for 411 participants; 170 had confirmed TB (41%). Point-of-care and laboratory-performed urine LAM had similar sensitivity (both 42%) and specificity (91% vs 88%).²⁵

TB LAM was also found to be cost effective in several settings with high rates of TB/HIV co-infection. A recent MSF-coordinated study in Kenya, as well as other studies in Uganda,²⁶ Malawi¹⁹ and South Africa,^{8,27,28,29} showed that TB-LAM increases the number of TB patients detected while reducing costs; including TB-LAM in diagnostic algorithms is cost-effective for severely ill or immunosuppressed HIV-positive patients.¹² The test could increase life expectancy according to a recent modelling study carried out by Kerkhoff et al.²² TB LAM enabled rapid TB diagnosis, which led to quick treatment initiation of more people living with HIV in Malawi, South Africa⁷ and Kenya¹⁸ than previous microscopy or Xpert alone.

A study by MSF in Democratic Republic of Congo, Malawi and Mozambique found that performing TB LAM is feasible in primary health centres (in rural and urban settings) as well as hospitals (including outpatient departments). The study showed that the turn-around time (TAT) for TB LAM

in the consultation room was 41 minutes versus 2 days for sputum-based tests, and that the TB LAM TAT allowed for same-day TB treatment initiation. The study also showed that more patients had a TB LAM test result (97%) than had a sputum-based test result (49%).³⁰

Abbott has registered TB LAM in 13 countries but only 7 of these countries have rolled out the tool nationally.³¹

FUTURE LAM TESTS

There are several novel LAM assays in the pipeline for diagnosis and treatment monitoring that could offer better performance than the currently available Determine TB LAM Ag test. The frontrunner currently undergoing trials is the Fujifilm SILVAMP TB LAM (FujiLAM) urine-based test, which has recently received CE marking.[†] In early accuracy studies, FujiLAM's sensitivity was demonstrated to be significantly higher than Alere TB LAM by 28%. These studies used biobanked frozen urine samples from 968 hospitalised people living with HIV with a median CD4 count of 86 cells per μL . Overall, FujiLAM's sensitivity and specificity was estimated to be 70% and 91%, respectively. FujiLAM's increased sensitivity was observed across the CD4 strata, indicating the possibility to expand use for this new test to detect TB in all people living with HIV.¹⁰

However, to save lives, scale-up of the current TB LAM test should continue, since FujiLAM is not expected to be available for use at the country level until it has undergone clinical trials assessing performance and feasibility and receives endorsement from WHO.

RECOMMENDATIONS

We encourage governments in high HIV/TB burden settings to:

- Scale up TB LAM nationwide in all outpatient and inpatient health facilities; TB LAM tests, training and consumables (e.g. pipettes, pipette tips, urine cups, timers) should be included and budgeted for.
- Rapidly develop nationwide implementation plans to roll out TB LAM (including forecasting plans) together with key stakeholders, such as implementing partners, civil society and donors.
- Update national TB and HIV guidelines and algorithms to reflect use of TB LAM to diagnose TB among people living with HIV in outpatient and inpatient settings.
- Update reporting and recording tools, such as TB laboratory registers, to reflect the TB LAM test.
- Plan nationwide training on the use TB LAM for laboratory and healthcare workers and ensure that health workers understand how to interpret test results.
- Provide an import waiver or exemption for TB LAM in lieu of registration, where needed.
- Encourage Abbott to register TB LAM, particularly where lack of registration hinders implementation of the test.

* The test can be conducted in approximately 25 minutes

† Conformité Européenne (CE) marking is a certification mark that is recognisable globally, which indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA.

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