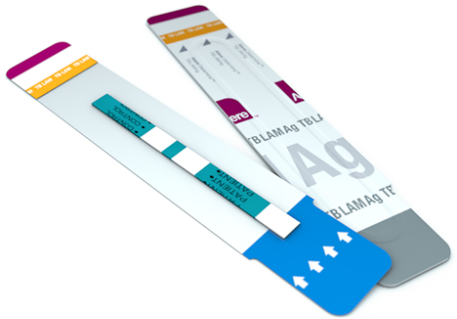


LAM assay: overview and practical guidance on its adoption and use

3 October 2017



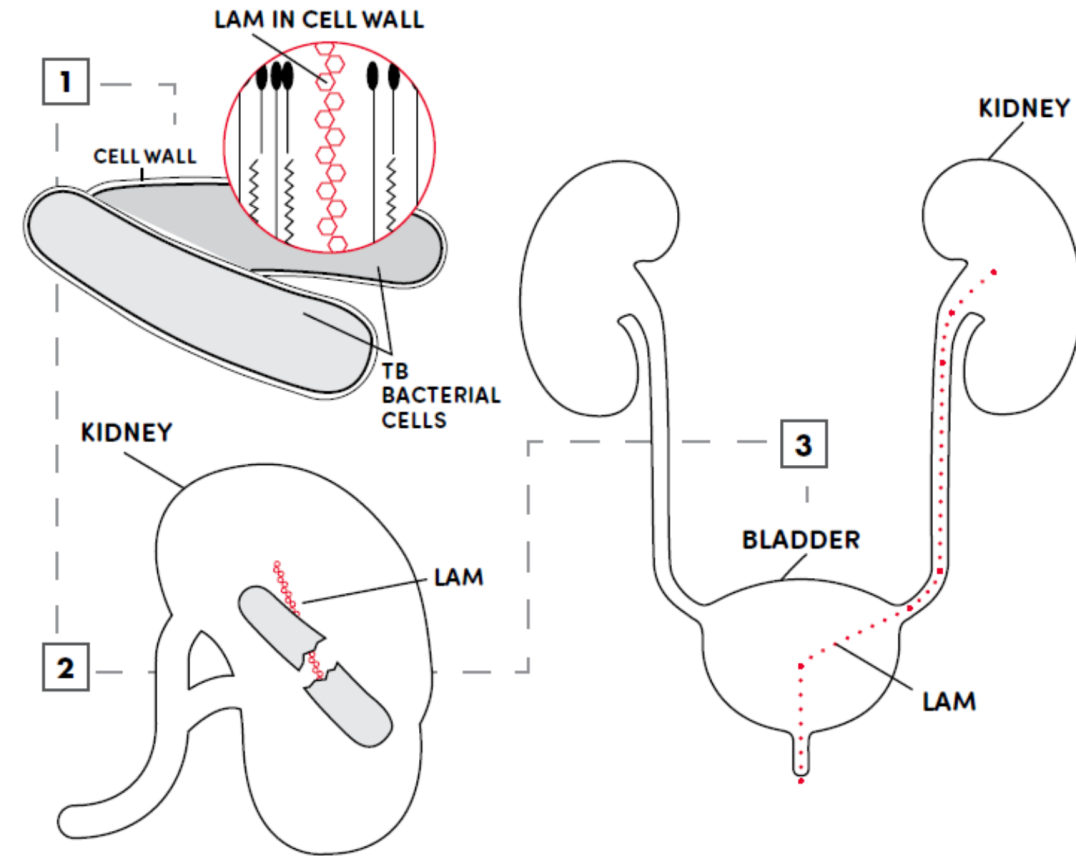
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Contents

- Overview of LAM and the assay
- Recommended use and placement in algorithms
- Resources available
- Practical information on procurement

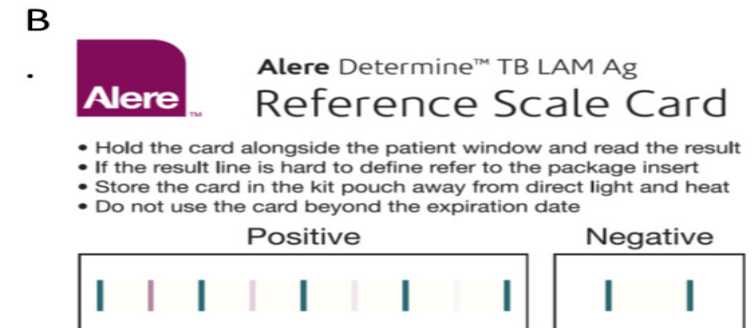
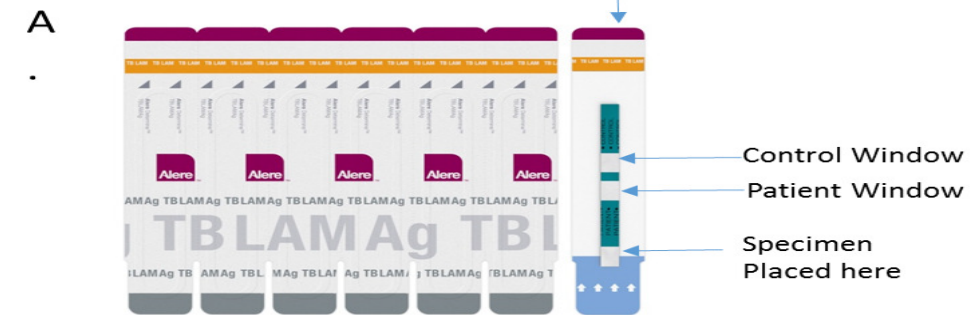
LAM: an overview

- Lipoarabinomannan (LAM) is a component of the cell wall of *M. tuberculosis*, and is released from metabolically active or degenerating bacterial cells
- In patients living with HIV and advanced immunodeficiency, disseminated TB with renal involvement can result in LAM in the urine
- A urine-based assay to detect LAM has important utility among these patients as they frequently do not have respiratory TB symptoms and/or are unable to produce sputum



LAM assay: an overview

- Simple dipstick test: only truly point-of-care (POC) test for TB
- Easy to collect and store urine; minimal biosafety hazards
- No infrastructural requirements or special equipment
- Rapid: results in 25 minutes
- Manufactured by Alere: Determine™ TB LAM ag
- Sensitivity has been found to increase with lower CD4 counts
- Has shown a significant decrease in mortality among HIV-positive hospital inpatients^a
- Some evidence of utility also among HIV/TB co-infected children^b

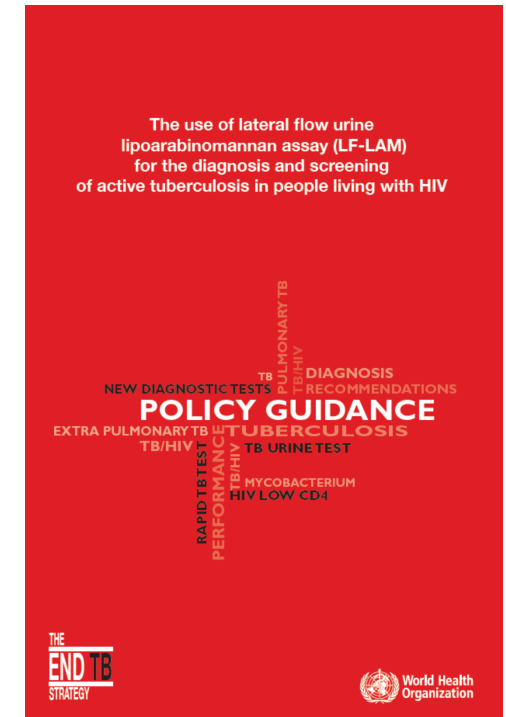


^a J. Peter et al, *Lancet* 2016; ^b I. Kroidl et al, *Eur Respir J* 2015 and A. Iskandar et al, *J Clin and Diag Res* 2017

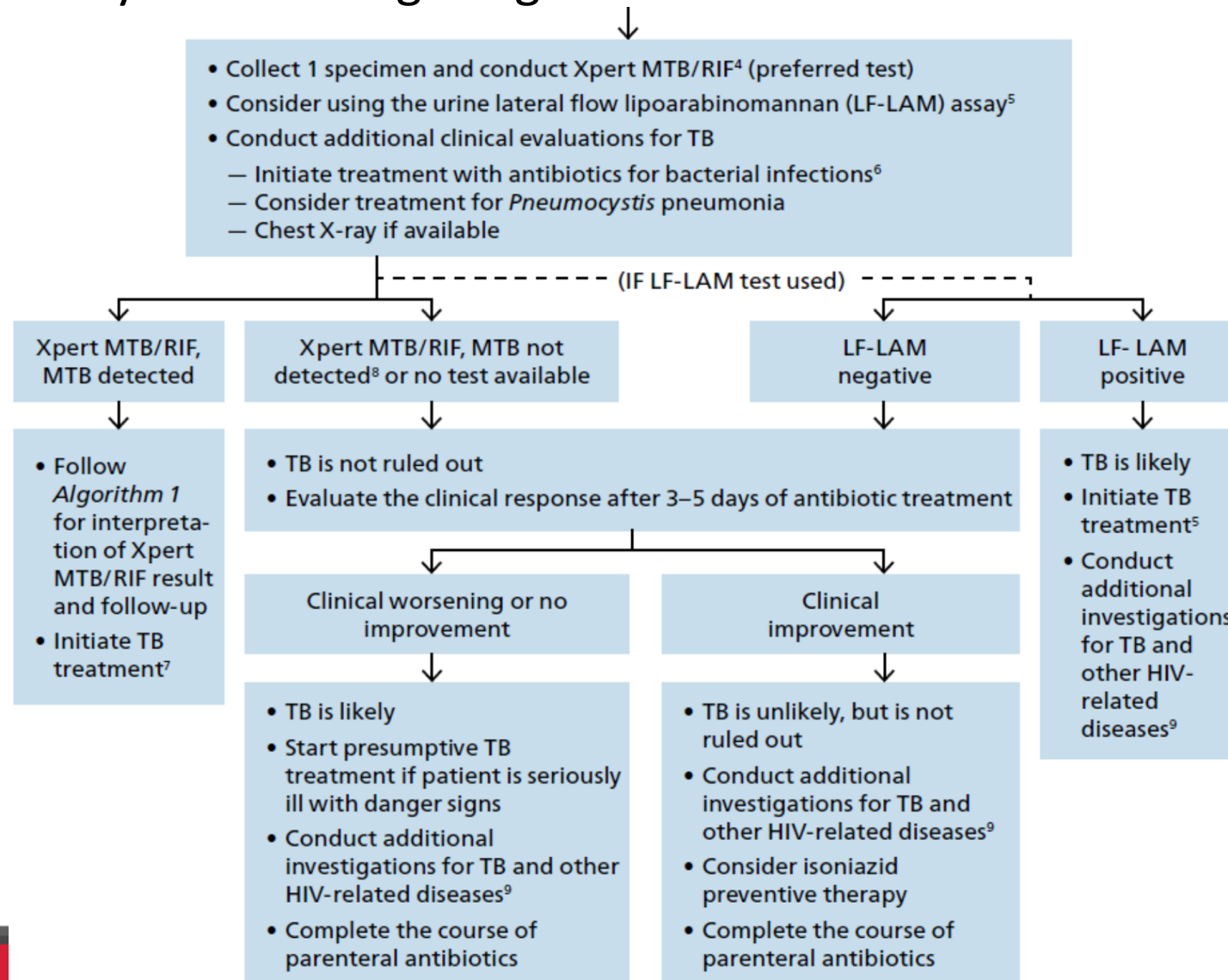
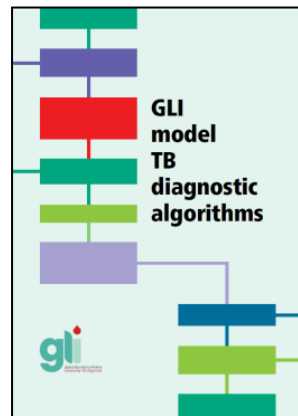
WHO recommendations

WHO Global TB Programme recommends use of the LAM assay to assist in the diagnosis of TB in two specific population groups:

- People living with HIV who have signs or symptoms of TB and a CD4 cell count less than or equal to 100 cells/ μ L
- People living with HIV who are “seriously ill” regardless of CD4 count or if the CD4 count is unknown. “Seriously ill” is defined based on 4 danger signs: respiratory rate >30 /min, temperature $>39^{\circ}\text{C}$, heart rate >120 /min and unable to walk unaided.
- Not recommended for TB screening or diagnosis of active TB disease in general population



GLI model TB diagnostic algorithm #4: Algorithm for evaluating persons for TB, among PLHIV who are seriously ill with danger signs or have CD4 counts ≤ 100 cells/ μ l



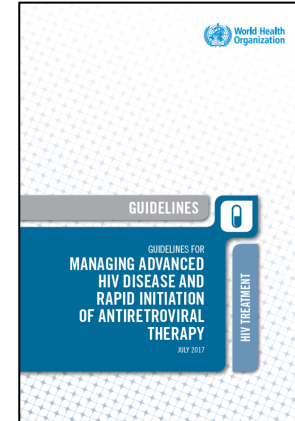
Footnote 5: “...Testing with the LF-LAM assay may be especially useful for patients unable to produce a sputum specimen. Whenever possible, a positive LF-LAM should be followed up with other tests such as Xpert MTB/RIF. While awaiting results of other tests, clinicians could consider initiating TB treatment immediately based on the positive LF-LAM and their clinical judgment.”

Resources available: current normative and practical guidance

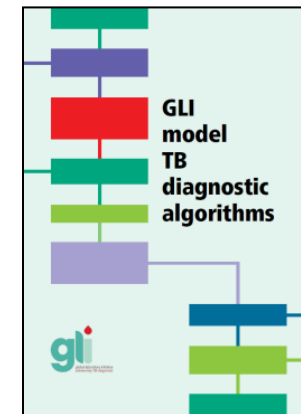


World Health Organization

- 2015 WHO Global TB Programme: Recommendations on use of LF urine LAM assay for the diagnosis and screening of active TB in PLHIV: <http://who.int/tb/publications/use-of-lf-lam-tb-hiv>
- 2017 WHO HIV Department: Guidelines on managing advanced HIV disease and rapid initiation of antiretroviral therapy (component of the package of care for people with advanced HIV disease): <http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease>



- 2017 GLI model TB diagnostic algorithms: Algorithm #4
- 2016 GLI Information note: *Study finds LF-LAM-guided TB treatment initiation reduces mortality in HIV-positive hospital inpatients*, including case studies on use of the LAM assay <http://stoptb.org/wg/gli/gat.asp>



TAG

Treatment Action Group

- 2017 TAG Activist's Guide to the TB LAM Test <http://treatmentactiongroup.org/content/activists-guide-tb-lam-test>



Procurement information

Alere Determine™ TB LAM ag (Alere Inc., USA)

Cost: US\$3.50 / strip (packaged in kits of 100 strips)

Shelf life: 18 months

Storage conditions: 2 – 30°C

Accessories required:

- Urine collection cups
- Pipette capable of delivering 60 µL and disposable pipette tips
- Timer

For information and direct orders: InternationalCustomerServiceTeam@Alere.com

GDF tender process underway; expected to be added to the GDF catalogue soon

Funding:

- Global Fund and PEPFAR will support the procurement of the test
- Stop TB Partnership's TB REACH will launch a call for proposals on **16 October:** NTPs and NGOs can apply for funding to roll-out LAM

Thank you

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