



Knowing now matters.™



The Alere Determine™ TB LAM Ag

Helping diagnose active Tuberculosis in HIV positive patients with results in just minutes.

TAP HERE TO SEE THE PRODUCT





Rapid Rule-in TB-HIV Co-infection

with the Alere Determine TB LAM Ag test

Now there is a new test to help detect active Tuberculosis (TB) in the HIV community. The Alere Determine TB LAM Ag test empowers you, at the point-of-care, to help diagnose active TB in HIV positive patients, providing results in just minutes. This novel rapid test detects the LAM antigen (lipoarabinomannan) in urine samples, assisting you in your TB screening to rule-in sooner than traditional methods and enabling earlier treatment for your patient.

TB + HIV = LAM

The Alere Determine TB LAM Ag test offers optimal performance in HIV positive patients with advanced immunosuppression. As the CD4 cell count declines, the sensitivity of the test increases, particularly in patients with CD4 cell counts below 200 cells/ μ L.¹ (Figure 1)

Detect sputum smear negative patients

HIV infected patients often have a lower sputum bacillary load, resulting in a higher proportion of sputum smear negative results. In a study of hospitalised HIV infected patients with advanced immunosuppression, the TB LAM Ag rapid test was able to detect more than half of the smear negative/sputum scarce patients.²

TB LAM Ag in Combination Increases Sensitivity

Enhanced diagnostic power comes through combination with methods such as sputum smear microscopy or the Xpert[®] MTB/RIF test.

Sputum smear microscopy

By combining TB LAM Ag and sputum smear microscopy, Lawn *et al*¹ were able to rule-in 72.2% of TB suspects with a CD4 cell count of less than 50 cells/ μ L. (Figure 2)

Xpert MTB/RIF

By combining the TB LAM Ag test with the Xpert MTB/RIF test, Lawn *et al*¹ demonstrated increased sensitivity, up to 83.3% in patients with CD4 cell count less than 50 cells/ μ L. (Figure 3)



Rapid test offers results in just 25 minutes

Figure 1*

Sensitivity (%) of the Alere Determine TB LAM Ag test in HIV infected patients

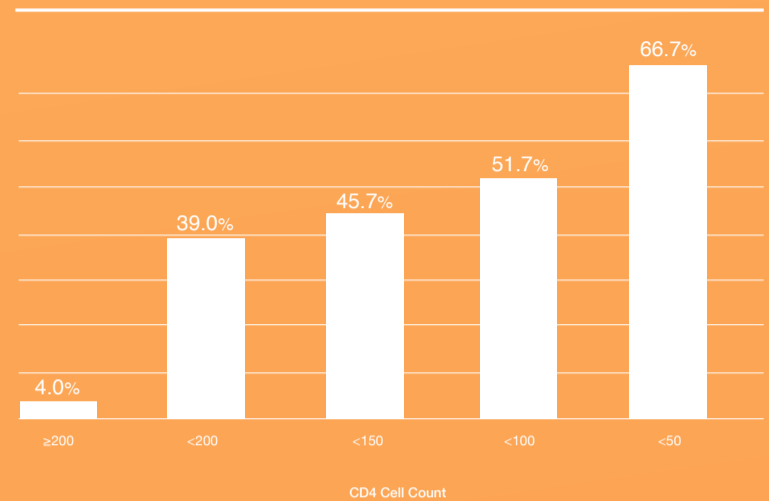


Figure 2*

Sensitivity (%) of TB Diagnostic Methods in HIV-TB co-infected patients

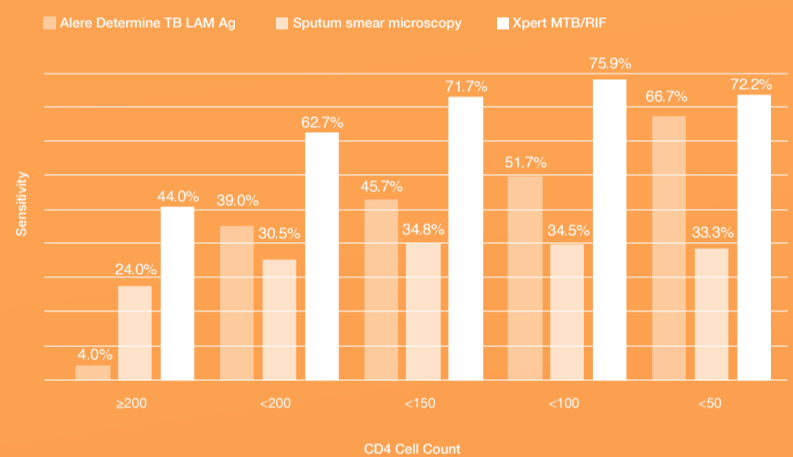
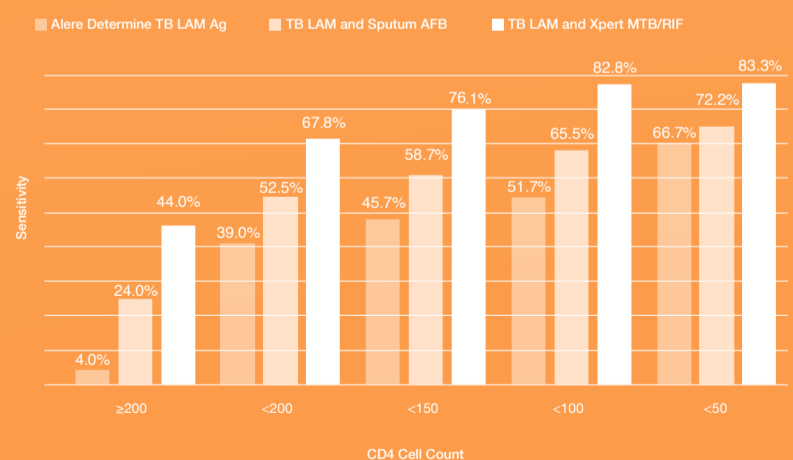


Figure 3*

Sensitivity (%) of Alere Determine TB LAM Ag when Combined





TB is the leading cause of death amongst HIV-infected patients.

Since the 1980s, the HIV epidemic has fuelled the resurgence of tuberculosis (TB) cases and deaths, particularly in sub-Saharan Africa. TB is notoriously difficult to diagnose in HIV-infected people. Traditional diagnostic methods such as sputum smear microscopy are insensitive, with a single sputum sample yielding sensitivity between 22-43%.⁴



Detect pulmonary and extrapulmonary TB

Urine is a convenient sample that is able to diagnose both pulmonary and extrapulmonary TB. HIV-infected patients often have a higher prevalence of extrapulmonary TB which is difficult to diagnose from a sputum sample.

Best performance in immunosuppressed patients

Sputum smear microscopy performs poorly in these patients, with sensitivity decreasing as the CD4 cell count drops. In contrast, the TB LAM Ag test offers the greatest sensitivity in the sickest patients.¹

Convenient urine sample

The Alere Determine™ TB LAM Ag test uses unprocessed urine as the validated sample type. Urine is an ideal sample as it is not specific to the location of an infection, it is readily available, it doesn't produce hazardous aerosols and poses a lower biohazard and infection risk to health care workers, laboratory staff and other patients.

Antigen detection test

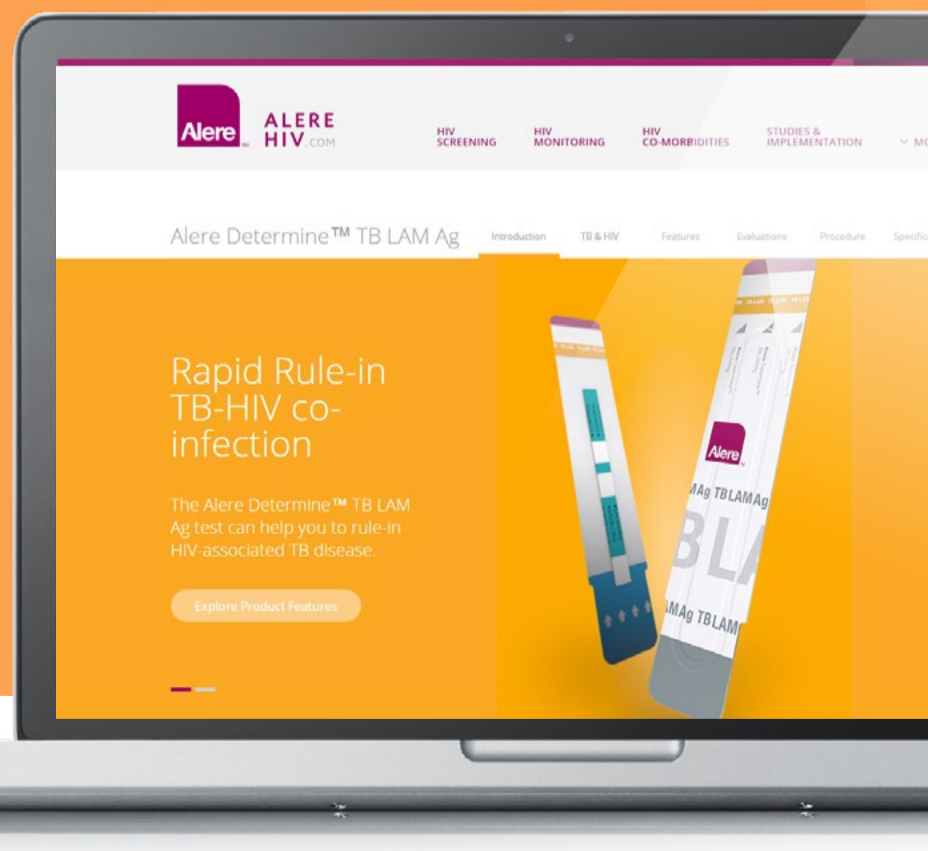
The Alere Determine TB LAM Ag test is an antigen (Ag) detection test, and detects the LAM antigen. It shouldn't be confused with commonly used TB antibody (Ab) serological tests. The WHO recommends against using TB antibody tests as they can adversely impact patient safety.³

TB LAM Antigen

LAM, lipoarabinomannan, is a structurally important component of the outer cell wall of mycobacteria. It is a 17.5 kDa glycolipid found at the surface of the cell.

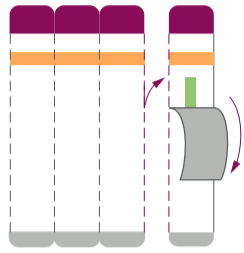
AlereHIV.com

Visit AlereHIV.com for in depth product features, videos from key opinion leaders detailing their studies and more interactive content on the Alere Determine TB LAM Ag test.

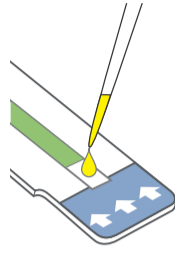


Procedure

- 1** Prepare Test
Tear one strip from the right and remove cover.



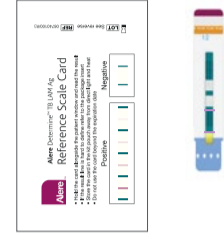
- 2** Add Sample
Apply **60 µL** of urine to sample pad.



- 3** Read Results
Wait 25 minutes and read the results.



- 4** Check Results
Against the Reference Scale Card.



Refer to the User Guide and Product Insert for complete instructions.

Product Information

Information Type	Product Detail
Method	Lateral flow
Time to results	25 minutes
Storage conditions	2 - 30°C
Shelf life	18 months
Sample type	Urine (unprocessed)
Kit contents	100 test units, Reference Scale Card, Package Insert

Ordering Information

Product Name	Product Code
Alere Determine TB LAM Ag (x100)	7D2740

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- Peter JG, Theron G, van Zyl-Smit R, Haripersad A, Mottay L, Kraus S, Binder A, Meldau R, Hardy A, Dheda K. Diagnostic accuracy of a urine LAM strip-test for TB detection in HIV-infected hospitalised patients. *Eur Respir J.* 2012 Feb 23 (Epub ahead of print).
- WHO Commercial Serodiagnostic Tests for Diagnosis of Tuberculosis, Policy Statement 2011 [Internet]. Geneva: World Health Organisation; 2011 [cited 2012]. Available from: http://whqlibdoc.who.int/publications/2011/9789241502054_eng.pdf.
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* Adapted from Lawn SD *et al.*, "Diagnostic accuracy of a low-cost, urine antigen, point-of-care screening assay for HIV-associated pulmonary tuberculosis before antiretroviral therapy: a descriptive study." *Lancet Infect Dis.* 2012 Mar;12(3):201-9.

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