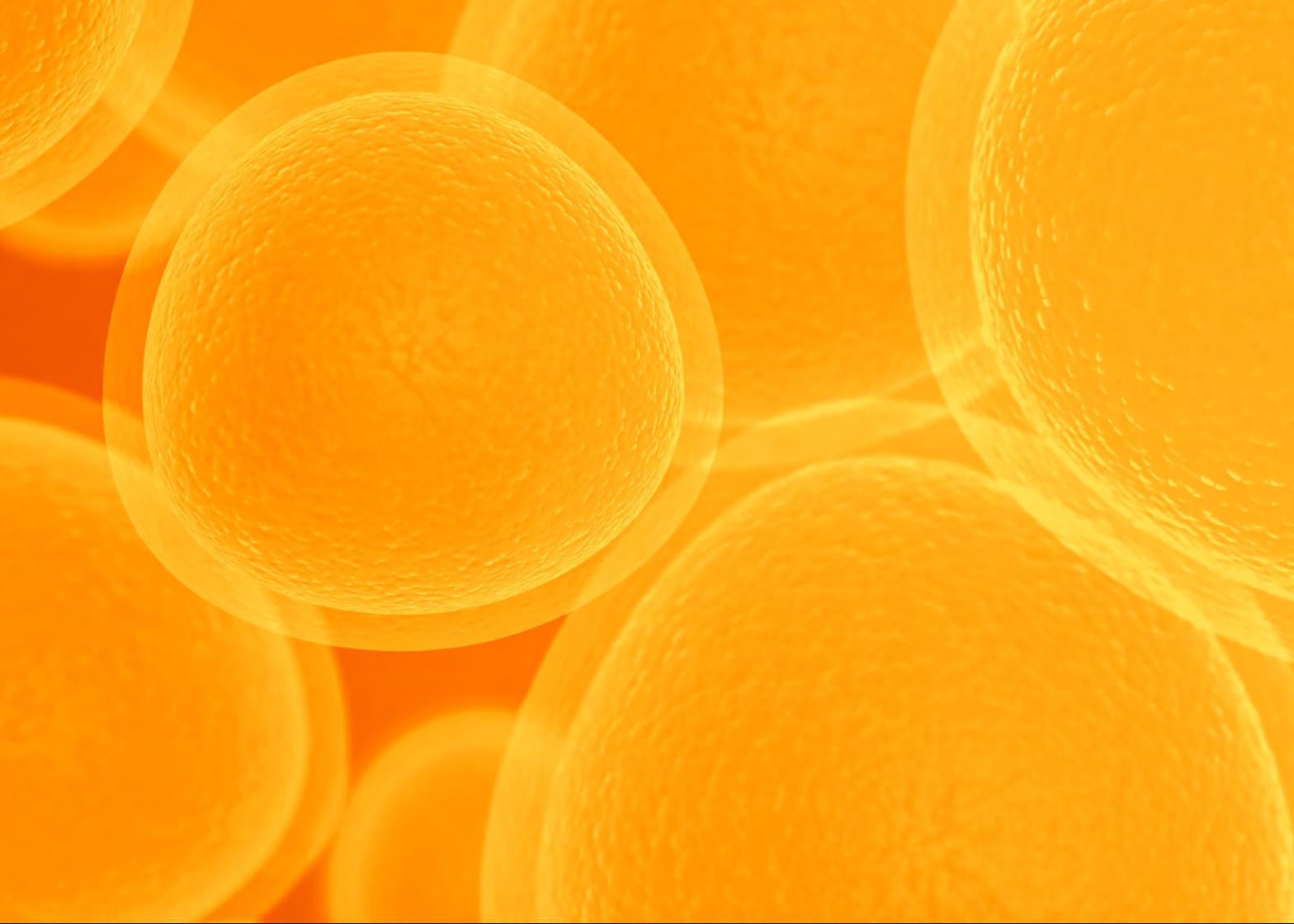# ALERE DETERMINE™
TB LAM Ag

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

Rapid Rule-in
TB-HIV Co-infection
with the Alere Determine
TB LAM Ag test

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, allowing you to make "rule-in" decisions, and thus enabling earlier treatment for your patient.

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

Since the 1980s, the HIV epidemic has fuelled the resurgence of tuberculosis cases and deaths. 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]

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/µL.[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 approximately one-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.[1]

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/µL. (Figure 1)

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/µL. (Figure 2)

FIGURE 1*

Sensitivity (%) of TB Diagnostic Methods in HIV-TB co-infected patients
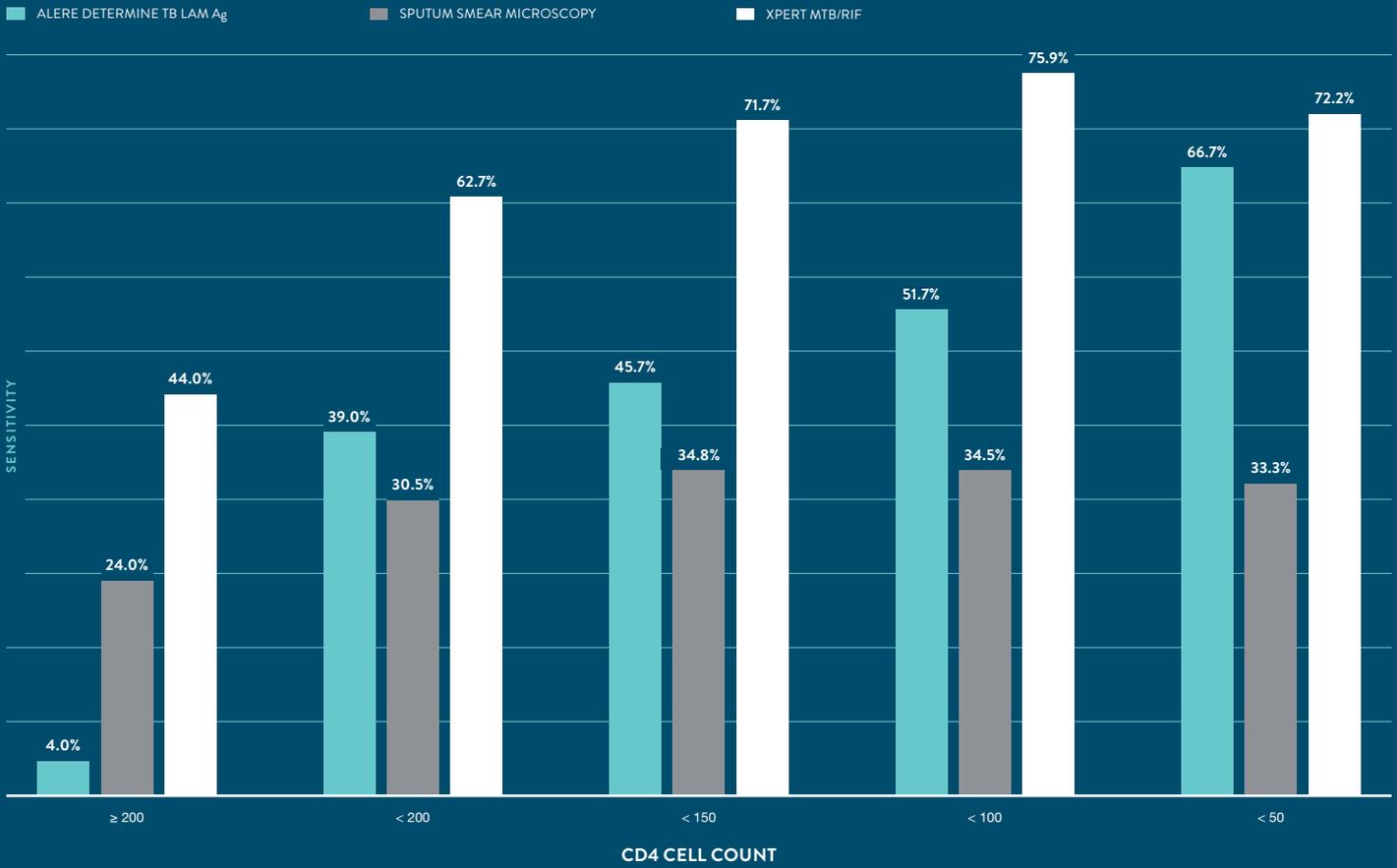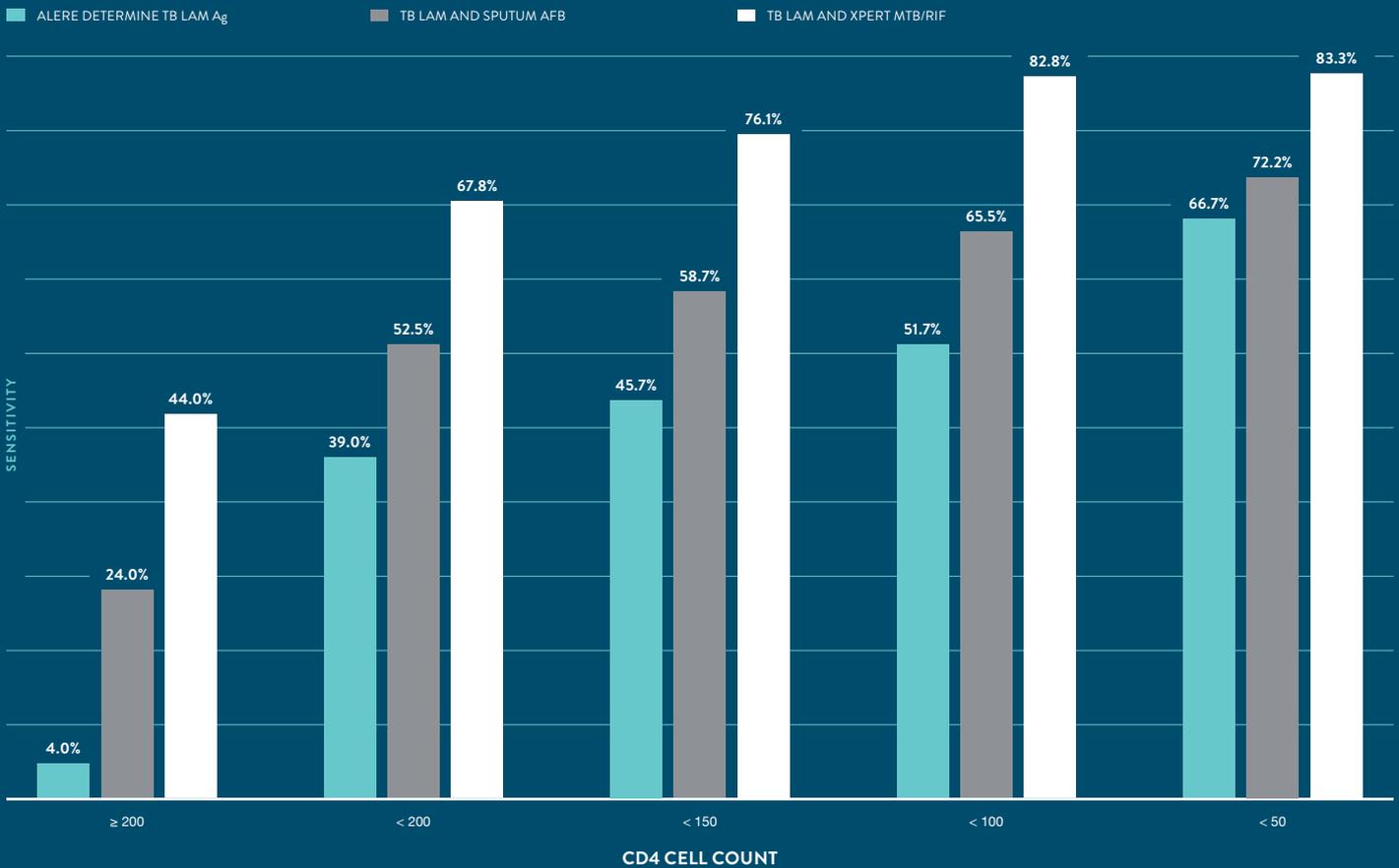
- ALERE DETERMINE TB LAM Ag
- SPUTUM SMEAR MICROSCOPY
- XPERT MTB/RIF

SENSITIVITY

CD4 CELL COUNT

CD4 CELL COUNT	≥ 200	< 200	< 150	< 100	< 50
Alere Determine TB LAM Ag	4.0%	39.0%	45.7%	51.7%	66.7%
Sputum Smear Microscopy	24.0%	30.5%	34.8%	34.5%	33.3%
Xpert MTB/RIF	44.0%	62.7%	71.7%	75.9%	72.2%

FIGURE 2*

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

- ALERE DETERMINE TB LAM Ag
- TB LAM AND SPUTUM AFB
- TB LAM AND XPERT MTB/RIF

SENSITIVITY

CD4 CELL COUNT

CD4 CELL COUNT	≥ 200	< 200	< 150	< 100	< 50
Alere Determine TB LAM Ag	4.0%	39.0%	45.7%	51.7%	66.7%
TB LAM and Sputum AFB	24.0%	52.5%	58.7%	65.5%	72.2%
TB LAM and Xpert MTB/RIF	44.0%	67.8%	76.1%	82.8%	83.3%

25 MIN

Rapid results in just 25 minutes

DETECT PULMONARY & 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.[2]

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 when compared to smear microscopy in the sickest patients.[1]

CONVENIENT URINE SAMPLE

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.

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]
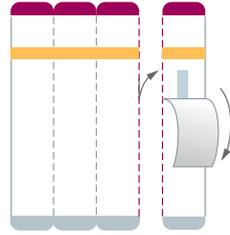
TB LAM ANTIGEN

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.[2]
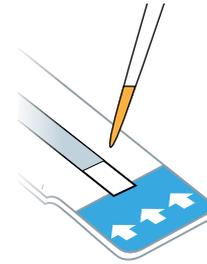
PROCEDURE

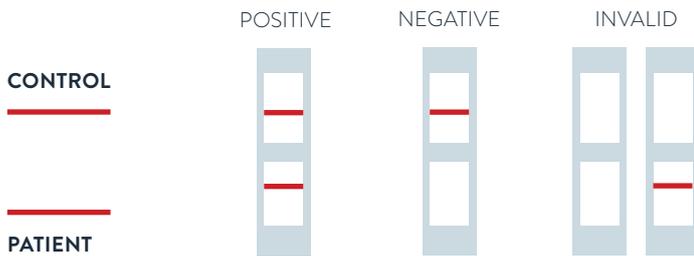*Refer to the User Guide and Product Insert for complete instructions.*

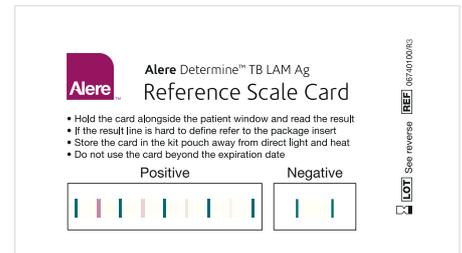## 1 Prepare Test
Tear one strip from the right and remove cover.

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

3 Read Results
Wait 25 minutes and read the results.

CONTROL

PATIENT

POSITIVE   NEGATIVE   INVALID

4 Check Results
Against the Reference Scale Card

Alere Determine™ TB LAM Ag
Reference Scale Card

REF 06740100R3

• Hold the card alongside the patient window and read the result
• If the result line is hard to define refer to the package insert
• Store the card in the kit pouch away from direct light and heat
• Do not use the card beyond the expiration date

Positive   Negative

LOT See reverse

PRODUCT INFORMATION

INFORMATION TYPE	PRODUCT DETAIL
METHOD	LATERAL FLOW
TIME TO RESULTS	25 MINUTES
STORAGE CONDITIONS	2 - 30°C
SHELF LIFE	17 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

Not cleared/approved or for sale in USA

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1. Lawn SD, Kerkhoff AD, Vogt M, Wood R. 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.

2. 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).

3. WHO Commercial Serodiagnostic Tests for Diagnosis of Tuberculosis, Policy Statement 2011. Available from: http://whqlibdoc.who.int/publications/2011/9789241502054_eng.pdf.

4. Getahun H, Harrington M, O'Brien R, Nunn P. Diagnosis of smear-negative pulmonary tuberculosis in people with HIV infection or AIDS in resource-constrained settings: informing urgency policy changes. Lancet. 2007 Jun 16;369(9578):2042-49.

*   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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