



Clearview TB ELISA

LAM SPECIFIC DIRECT ANTIGEN TEST

**The fightback
against TB and HIV
can start right here.**



Clearview®

Clearly different. **Clearly better.**

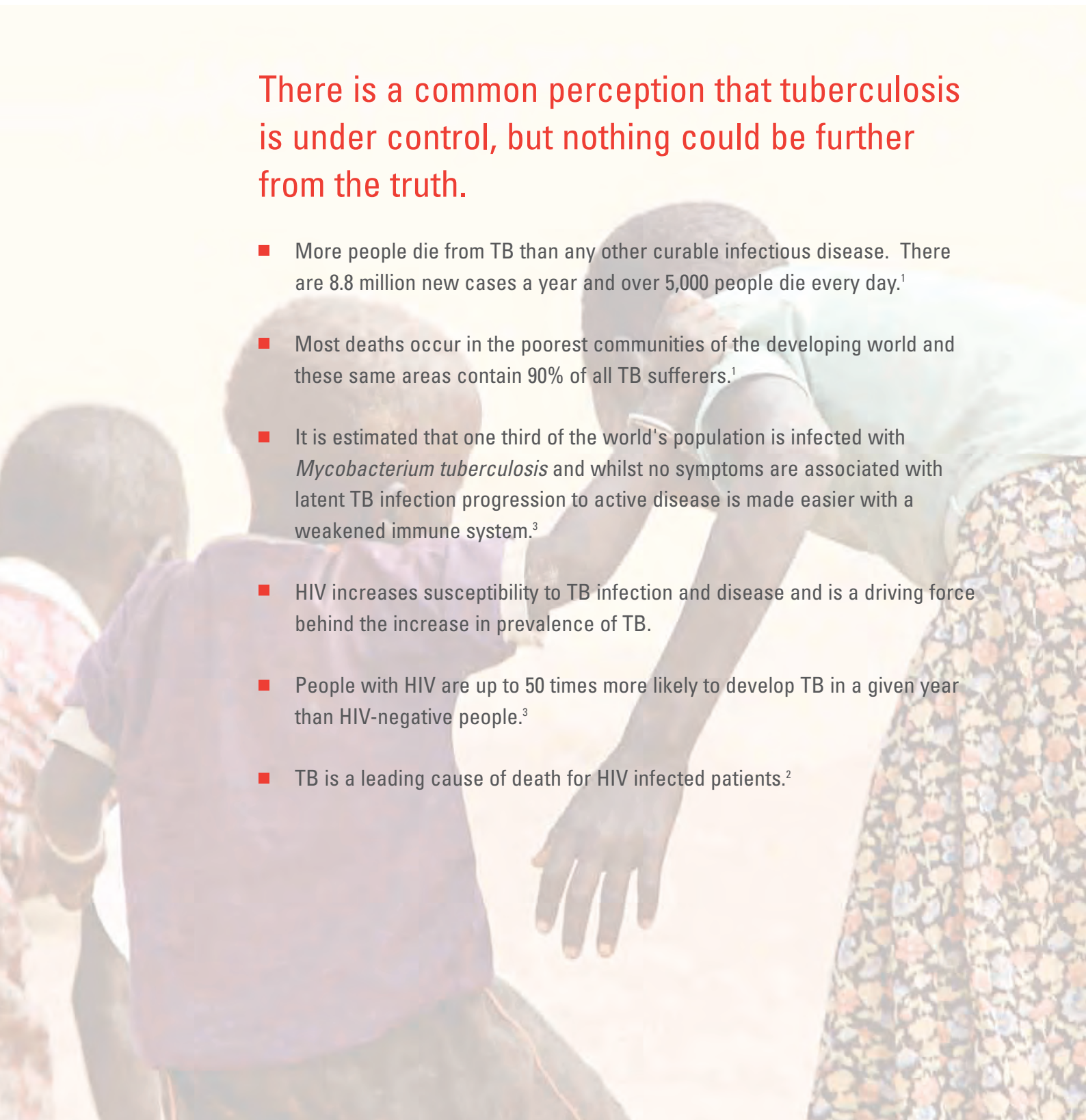


The Challenge Posed by TB/HIV

HIV/AIDS and TB are so closely connected that they are often referred to as co-epidemics or dual epidemics³

There is a common perception that tuberculosis is under control, but nothing could be further from the truth.

- More people die from TB than any other curable infectious disease. There are 8.8 million new cases a year and over 5,000 people die every day.¹
- Most deaths occur in the poorest communities of the developing world and these same areas contain 90% of all TB sufferers.¹
- It is estimated that one third of the world's population is infected with *Mycobacterium tuberculosis* and whilst no symptoms are associated with latent TB infection progression to active disease is made easier with a weakened immune system.³
- HIV increases susceptibility to TB infection and disease and is a driving force behind the increase in prevalence of TB.
- People with HIV are up to 50 times more likely to develop TB in a given year than HIV-negative people.³
- TB is a leading cause of death for HIV infected patients.²





“Without the right diagnostic tools we cannot stop the TB epidemic.” World Health Organization¹

The inability of many patients in the developing world to access adequate diagnostic tools at their local health services often leaves them undiagnosed or misdiagnosed and able to infect members of their family and local community. In such peripheral health settings, primary screenings for TB are non-existent or limited to sputum microscopy.

Microscopy examination

- As a diagnostic tool has remained relatively unchanged for the past 100 years.
- Requires the analysis of multiple samples often taken on different days.
- Requires sufficiently trained personnel and adequate equipment maintenance.
- Microscopy sensitivity ranges between 40%-60% and falls to as low as 20% in patients who are also HIV infected.¹
- TB/HIV patients are often unable to produce sputum for use in microscopy.

Other diagnostic tools

- Chest x-rays, bacteriological culture and nucleic acid amplification require trained technicians and sophisticated medical equipment.
- The delay in securing an accurate diagnosis and commencement of targeted treatment can lead to further disease transmission.



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Meeting the Challenge of TB and HIV

Faster, more reliable diagnostic tools are needed by healthcare professionals to combat the rise of TB, particularly in areas with high incidence of HIV infection.

The limited resources currently available can often be wasted on misdiagnosis and repeat or untargeted treatments, which also directly contribute to the worrying growth of multi-drug resistant TB. Clearview TB ELISA is a breakthrough step towards offering healthcare professionals the tools needed to diagnose TB in HIV co-infected patients.

- Better diagnosis improves disease detection rates, aids accurate diagnosis, reduces the threat of transmission and brings fewer early deaths in patients also infected with HIV.
- Clearview TB ELISA uses antibodies specific to the mycobacteria antigen lipoarabinomannan (LAM) which forms part of the TB cell wall. The elevated levels of the LAM antigen in the urine of TB/HIV patients provides a specific diagnostic target.
- The use of urine also offers the clinician the advantage of a sample material which is safer and far less invasive than conventional sputum sample collection.



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Product Benefits

Rapid

- Clearview TB ELISA is a revolutionary urine-based test that improves the speed in detecting the disease amongst HIV patients and can play a crucial role in slowing the spread of TB across the developing world.
- Results are available in less than 3 hours

Accurate

- Clinical study has demonstrated better performance in the field than the current standard of sputum microscopy in patients co-infected with TB and HIV and is significantly easier to use than other methodologies.⁴
- Clearview TB ELISA clinical trial data has shown over 80% sensitivity in HIV positive patients.⁵

Specific

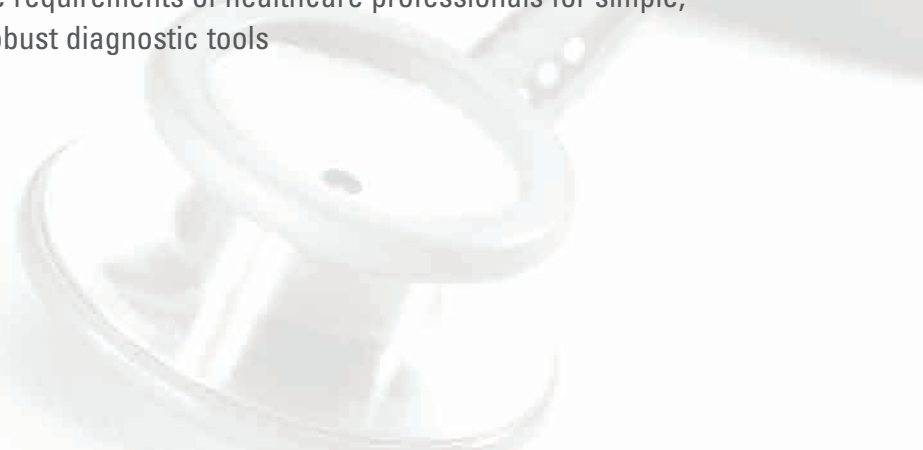
- In clinical trials Clearview TB ELISA displayed over 90% specificity in healthy controls.⁵

Easy to use

- Requires just one patient visit for sample collection

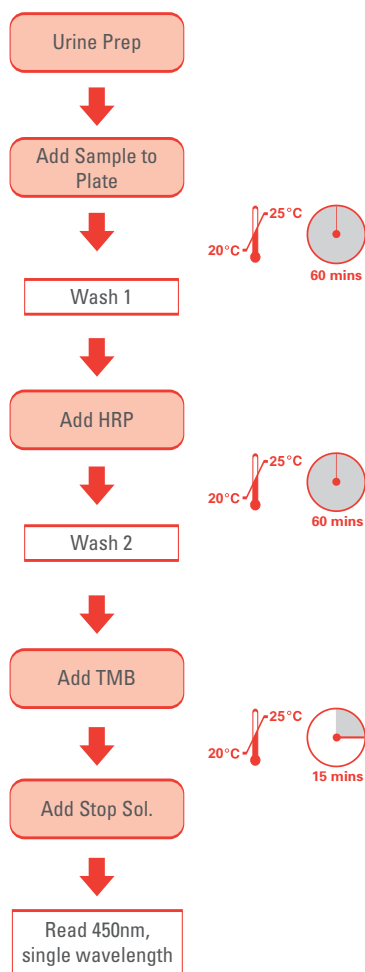
Our Expertise

- Inverness Medical manufactures high quality rapid HIV diagnostic tests and understands the requirements of healthcare professionals for simple, accurate and robust diagnostic tools



Procedure:

Clearview TB ELISA is an enzyme-linked immunosorbent assay (ELISA) based system that qualitatively detects the presence of lipoarabinomannan (LAM) antigen of mycobacteria in human urine as an aid in the diagnosis of mycobacterial infection in patients with HIV.



Catalogue number:

M913

Kit contents:

96-well Microtiter Plate
1 Chromogenic Substrate Solution
1 HRP Conjugate Solution
1 Negative Control
1 Positive Control
1 PBST Dry Buffer Pouch
Package Insert

Storage and shelf life:

2-8 °C

Sample type and preparation:

Urine. Collect in standard urine collection container and process within 24 hours

Time to result:

Less than 3 hours

References:

- 1 *Diagnostics for Tuberculosis: Global Demand and Market Potential.* World Health Organization, 2006.
- 2 WHO Fact Sheet #104 (revised March 2007).
- 3 WHO TB/HIV <http://www.who.int/tb/challenges/hiv/qa.pdf> (May 2008).
- 4 Boehme C et al. *Detection of mycobacterial lipoarabinomannan with an antigen-capture ELISA in unprocessed urine of Tanzanian patients with suspected tuberculosis.* Trans R Soc Trop Med Hyg. 99 (12):893-900, 2005.
- 5 See Package Insert.

Distributed by:



NL Charles Stulemeijerweg 15, 5026 RS Tilburg
T 013 467 27 00 F 013 467 80 16
B Rond Point Schuman 6, 1040 Brussels
T 02 280 05 06 F 02 280 06 61
orange@orangemedical.nl www.orangemedical.nl



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Clearly different. **Clearly better.**

www.clearview.com

Unipath Limited, Bedford MK44 3UP, United Kingdom
Tel: +44 (0)1234 835000 Fax: +44 (0)1234 835009

