



Value proposition

- Requires a single drop of blood (instead of sputum) to diagnose TB;
- Early-stage detection, when the disease is most curable;
- Can be done at the point of care;
- 100% specific; more than 80% sensitive (actual patient data);
- Accurate regardless of the patient's HIV status;
- Detects TB infection inside and outside the lungs;
- Result is known less than one hour after the blood sample has been taken;
- Cost per analysis is similar to (or lower than) existing diagnostics.

This diagnostic could result in significant savings to the public healthcare system in South Africa and worldwide. The speed of analysis and the ability to perform it at the point of care will alleviate the need to hospitalise a presumptive TB patient for the purpose of obtaining a sputum sample or to await the outcome of the diagnostic analysis.

The MARTI test can be used to screen large populations, for example schools, prisons, migrants and travelers at the point of entry.

Market

More than 88 million TB diagnosis tests are performed annually in the 'BICS' countries: Brazil, China, India and South Africa. This constitutes a US\$480 million per year market. The World Health Organisation (WHO) has estimated the global TB diagnosis market at more than US\$1 billion, or more than 130 million tests per year.

Source: TB Diagnostics Market in Select High-Burden Countries, UNITAID & WHO, 2015

Blood-based TB diagnosis

Previously, concerns have been raised about the accuracy of TB diagnostics based on blood-based detection of antibodies. However, those methods were all based on anti-*protein* antibodies while the MARTI test is wholly based on anti-*lipid* antibodies.

The human body's best known protective antibody response to most infectious agents is directed to *protein* antigens. Production of antibodies to protein antigens is facilitated by antibody-producing B-cells that display the antigen first to CD4 'helper' T-cells. Helper T-cells are targeted and paralysed by HIV.

In TB patients, antibodies are directed also to lipid (fat-based) antigens such as mycolic acid. B-cells that produce antibodies directed to *lipid* antigens do not require help from CD4 T-cells, hence providing an alternative pathway of antibody generation that is not affected by HIV co-infection. Therefore concerns about TB diagnosis using blood-based detection of antibodies do not apply to the MARTI test.



Prof Anton Stoltz
Chief clinician
Head of Infectious
Disease, Steve Biko
Academic Hospital

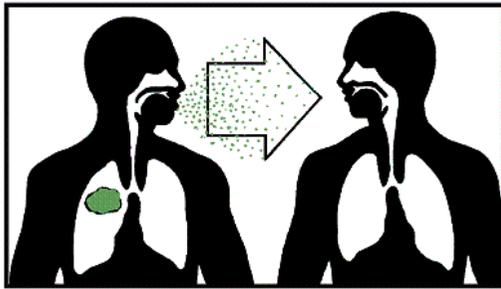


Prof Jan Verschoor
Chief scientific advisor



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UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

MARTI TB Diagnostics (Pty) Ltd is a start-up venture of the
University of Pretoria



The challenge of TB diagnosis

TB is a curable disease provided it is diagnosed sufficiently early. In South Africa and many other countries vast numbers of people still die from TB. Early and accurate diagnosis can significantly alleviate this problem. Practically all commercial TB diagnosis techniques currently in use require a sputum sample, which is usually collected through induced coughing. Sputum sampling is undesirable for the following reasons:

- It poses a significant risk to healthcare workers since the highly infectious TB bacteria are mostly airborne;
- It is very difficult to obtain sputum from children and HIV-infected patients;
- In 16% of patients the TB occurs outside the lungs, hence it is not detectable in sputum.

A diagnostic *not* based on sputum holds significant advantages. MARTI is the only TB diagnostic based on detecting a *specific* antibody in the blood to diagnose TB at an early stage of infection.



Carl Baumeister
Head of Operations



Gerrie Mostert, CEO



Ikechukwu Okeke
Biochemical analyst



Suite BA11, Gauteng Biopark, Allan Cormack Street,
The Innovation Hub, Pretoria, South Africa

Tel: +27 (0)12 844-0178 / 9

Email: info@martidiagnostic.com

Web: www.martidiagnostic.com



www.martidiagnostic.com