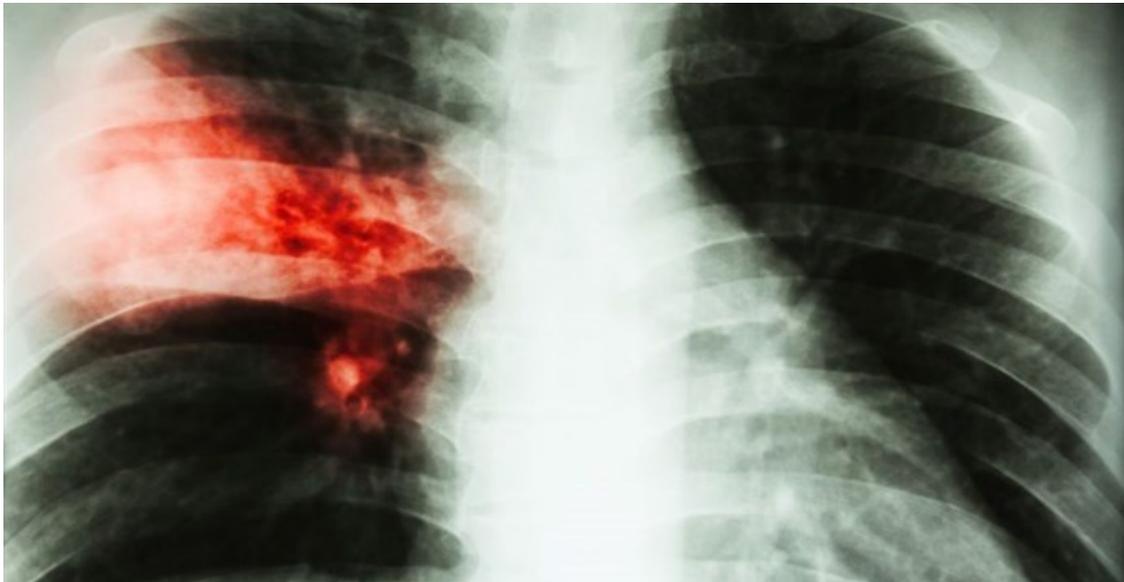


# New transcriptomic blood test to screen and monitor for TB

A new simple blood-based test that can identify healthy individuals who are at risk of developing tuberculosis (TB), identify those with subclinical or clinical disease, and can inform how well a patient would respond to treatment.



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The 6-gene RNA biomarker, known as RISK6, was validated in seven independent cohorts across two continents using quantitative real-time (qRT) polymerase chain reaction (PCR).

Researchers from the South African Tuberculosis Vaccine Initiative (SATVI) at the University of Cape Town, the Center for Infectious Disease Research in Seattle, and a large consortium of collaborators have also demonstrated that the test, which can be applied to capillary blood collected by finger prick, could be developed into a rapid, fingerprick blood-based test device for use at the point of care. This advance paves the way for point-of-care field evaluation and implementation studies of this test in community and primary care settings.

## Lacking in tools and tests

More than 1.7-billion persons are estimated to be infected with the bacterium *Mycobacterium tuberculosis* globally, of which 10-million developed TB disease and over 1.4-million died in 2018 (WHO Global TB Report 2019). Current diagnostic tools rely on the detection of *Mycobacterium tuberculosis* in sputum, which is only possible in people with advanced disease and who can produce sputum samples. We currently do not have any effective tests that can detect the bacterium or the disease in people who are not symptomatic. We also do not have tests that can predict which healthy individuals who are infected with the bacterium (latent TB), will progress to TB disease. Effective tools to monitor the response to TB treatment are also lacking.

There is growing awareness in the scientific community that to reduce Mycobacterium tuberculosis transmission and curb the infection rate, individuals with TB disease need to be found much earlier during their disease progression, ideally before they develop symptoms. Even better, a prognostic test that can identify healthy individuals who are at high risk of progression to disease would allow a physician to prescribe a targeted course of preventive antibiotic treatment before transmission occurs, preventing individuals with TB from infecting others.

In South Africa it is estimated that the average person with TB can infect up to 10 people before being diagnosed and receiving treatment. Such a prognostic test would allow more efficient use of TB preventive therapies. In South Africa, as in many developing countries, where 60-80% of sections of the population are infected with the bacterium, latent TB is not treated as part of the standard of care, because treating such vast numbers is not feasible.

## **Monitoring treatment**

In addition, RISK6 scores correlated with degree of lung immunopathology, measured by positron emission tomography, and tracked TB treatment response, demonstrating utility as treatment response biomarker. RISK6 also allowed identification of patients with failed TB treatment prior to treatment initiation, demonstrating that a blood test may be used to guide or adjust TB treatment to achieve better efficacy. The study also showed that performance of the test in capillary blood samples collected by finger-prick was non inferior to venous blood collected in PAXgene tubes. RISK6 has the potential to fill a critical gap in tools required to achieve non-sputum screening of communities to identify those at greatest need for treatment, and to monitor treatment response.

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