

A Blood-based Diagnostic for Active Tuberculosis and Predicting Progression from Latent to Active Disease

Tuberculosis diagnosis remains challenging, particularly distinguishing between active and latent infection. Misdiagnosis drives unnecessary antibiotics use, and disproportionately affects HIV-positive patients who have the greatest clinical need for accuracy. Clinical diagnostics rely on sputum testing, making sample collection difficult in children and non-symptomatic individuals.

Stanford researchers have developed a blood-based tuberculosis assay that distinguishes between active and latent infection and identifies latent patients likely to progress to active disease within 12 months. Derived from transcriptional profiling of nearly 4,000 heterogeneous blood samples, a panel of nine transcriptional markers detects active infection at sensitivity and specificity exceeding WHO standards, while remaining effective in HIV-positive patients. The panel's output is condensed into a single score, adjustable for different clinical settings such as screening versus treatment monitoring. This approach shifts from pathogen detection to host immune profiling, offering a more robust and universally applicable TB diagnostic tool.

Stage of Development - Research In Vivo

Diagnostic markers have been independently validated in prospective and retrospective data sets.

Applications

- Screening assay for patients exposed to tuberculosis

- Monitoring assay for tuberculosis patients in treatment

Advantages

- Greater sensitivity than existing tuberculosis assays- Distinguishes latent from active TB
- Blood based - No dependence on sputum collection
- Rapid risk assessment in infectious disease patients
- High sensitivity in HIV-positive patients
- Treatment monitoring potential

Patents

- Published Application: [WO2022235518](#)
- Published Application: [20240218457](#)

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