# ENDxTB

Evaluation of new diagnostics for incident, active, and recurrent TB

FACT SHEET

### Acronym
ENDxTB

### Full Title
Evaluation of new diagnostics for incident, active, and recurrent TB

### Programme
National Institutes of Health (NIH)

### Grant number
1U01AI152075

## ABSTRACT

A central component of WHO's End TB Strategy is to diagnose approximately 3 million patients annually who are not diagnosed or treated due to inadequate tests that are not tailored towards specific needs for different levels or capabilities of health care facilities.

Better tests are needed at point-of-care, where triage in low-resource settings is essential to prioritise those with the highest risk for tuberculosis disease to higher levels of care. On the other hand, more complex, resource-intensive tests aimed at specific phases of host-pathogen interaction, like at the end of treatment or during latent infection would complement community-based diagnosis in less-developed health care systems that have access to central, specialised laboratory facilities.

Wide-ranging diagnostic capacities co-exist in different regions of the same country, for instance in rural versus urban areas and therefore, a comprehensive battery of diagnostic tests that are appropriate for specific settings are needed. Meeting the End TB Strategy targets will also require dramatically improved prevention of disease approaches to block transmission. With 1.7 billion people latently infected, it is not cost-effective to provide prophylaxis to all. Hence a test that could predict those most at risk of developing disease would enable targeted therapeutic approaches. Similarly, tests to enable personalised or stratified treatment strategies are urgently needed.

The goal of ENDxTB is to conduct a clinical research program across the globe to compare side-by-side the most promising new tests for a wide range of health care settings in experienced clinical sites in Africa (South Africa, The Gambia), and Southeast Asia (Vietnam), and advanced laboratories in the USA and Europe. The cohorts include adults, children, and people living with HIV. The new assays include: 1) at point-of-care: sputum-free assays, including two triage tests, based on detection of host proteins and host transcripts, both on fingerstick blood, and a

high-sensitivity urinary lipoarabinomannan assay; and 2) at central laboratories: a multiplex qRT-PCR test for mRNA signatures for progression to tuberculosis, and a host 4-protein biosignature in blood for prediction of poor treatmeht outcome.

The performance of these tests will be evaluated according to internationally established target product profiles for the respective health care levels. ENDxTB Project will identify the best tests for different health care levels and for different phases of infection and disease. The multi-disciplinary team of test developers and clinical scientists, and the selection of cohorts are well suited to identify novel technologies towards meeting the End TB milestones.

## Duration
68 months (17/06/2020 - 31/01/2026)

## Project Funding
7,499,882 USD

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