ADVANCEMENTS IN TB TESTING

CURRENT AND FUTURE LANDSCAPE OVERVIEW

The current diagnostic landscape for tuberculosis (TB) involves a two-step process that screens and diagnoses patients. However, **challenges** such as false positives due to Bacillus Calmette–Guérin (BCG) vaccination, higher costs, and reduced sensitivity persist. **New introductions** in diagnostics are focused on addressing these challenges and **include molecular tests for disease and drug resistance, interferon-gamma release assays (IGRAs) for infection detection, and biomarker-based assays.** Furthermore, **WHO's End TB Strategy**, which aims to achieve a TB-free world by 2035, focuses not only on reduction of incidence and death rates but also on alleviation of financial burden on patients and caregivers.

CURRENT LANDSCAPE

Patients undergo initial screening with skin/blood tests, followed by confirmatory testing until TB diagnosis is certain. However, this approach results in sensitivity, cost, and false positive challenges from BCG vaccination.

What Happens In This Phase

For a **TB skin test**, a small tuberculin dose is injected subcutaneously. Swelling at the site is examined 48–72 hours later. Positive: Possible TB, influenced by vaccination; negative: No swelling, minimal reaction

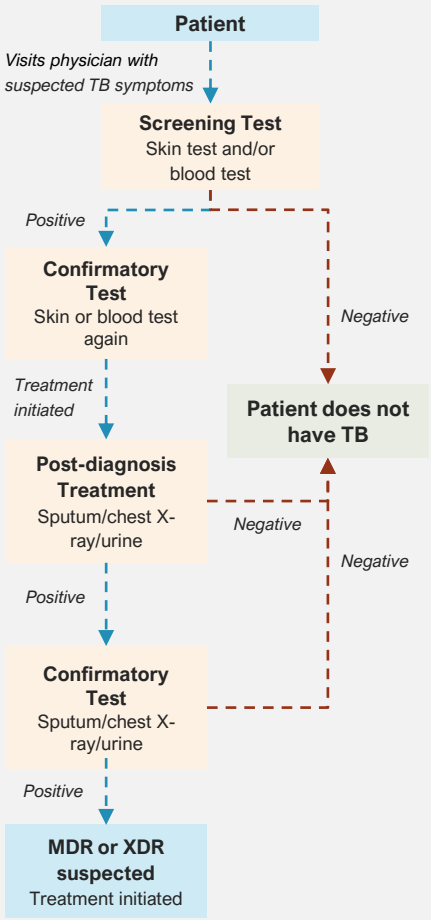
In a **TB blood test,** blood is drawn and exposed to TB-specific antigens. It measures the release of interferon-gamma. Positive: Possible TB infection

A **TB sputum test** involves providing a sample of mucus coughed up from the lungs. The sample is examined for the presence of mycobacterium.

A **chest X-ray for TB** examines the lungs for signs of infection. Abnormalities such as lung infiltrates or cavities might indicate active TB disease.

A **urine test for TB** detects mycobacterial antigens in urine samples. It is particularly useful for diagnosing disseminated or extrapulmonary TB, which affects organs other than the lungs.

Testing Algorithm



Current Unmet Needs

False positives due to BCG vaccination, subjectivity in reading results, delayed reading times, and false negatives in immunocompromised individuals

Higher cost compared to skin test and limited sensitivity in immunocompromised individuals

Lower sensitivity, especially in cases of paucibacillary TB or extrapulmonary TB

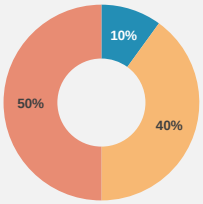
Challenges with TB chest X-rays include potential for false positives from other lung conditions, variations among radiologists' interpretation, and inability to distinguish between active and latent TB

Unmet needs with TB urine tests include **developing tests with higher sensitivity** to various forms of TB and enhancing accuracy to reduce false negatives

End TB Strategy 2025 Milestones

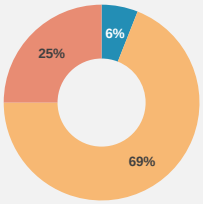
Focus on reducing TB incidence, deaths, and financial burdens while addressing challenges in diagnosis and treatment

TB incidence rate (IR)



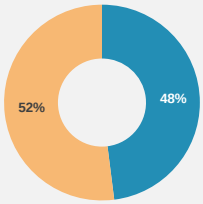
- % Reduction in IR achieved by 2021
- % Additional reduction in IR to be achieved by 2025
- % Remaining IR post 2025

Number of TB deaths



- % Reduction in deaths achieved by 2021
- % Additonal reduction in deaths to be achieved by 2025
- % of death cases still remaining post 2025

People facing TB catastrophic costs



- % Reduction in number of people facing treatment catastrophic costs achieved by 2021
- % Additional reduction in number of people facing treatment catastrophic costs to achieve by 2025

Reduce TB incidence rate	***~50%***
Reduce number of TB deaths	***~75%***
Reduce number of people facing TB catastrophic costs	***~100%***

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CURRENT AND FUTURE TECHNOLOGICAL LANDSCAPE

WHO is actively guiding the development of new TB diagnostics, including molecular tests for disease and drug resistance, IGRAs for infection detection, and biomarker-based assays.

CURRENT LANDSCAPE

FUTURE LANDSCAPE

Marketed Technologies not Evaluated by WHO

Molecular detection of TB disease and/or drug resistance detection

- iCubate System (iCubate, US)
- Genechip MDR test (Capital Bio, China)
- AccuPower TB&MDR Real-Time PCR Kit (Bioneer, South Korea)

IGRAs for TB infection detection

- Quantiferon (Diasorin, US)
- Lioferon TB/LTBI (Lionex Diagnostics & Therapeutics, Germany)
- VIDAS TB-IGRA (bioMérieux, France)

CAD for digital chest radiography

- Genki (Deeptek, US)
- XrayAME (Epcon, Belgium)
- InterRead DR Chest (InferVISION, China)

Technologies Under Evaluation by WHO

Culture-based drug susceptibility testing

- SensititreTM MYCOTBI plate (ThermoFisher Scientific Inc., US)

Culture-free, targeted-sequencing solutions for TB drug resistance detection

- Deeplex Myc-TB, (GenoScreen Innovative Genomic, France)

Biomarker-based assays for TB disease detection

- Fujifilm SILVAMP TB LAM Assay (Fujifilm, Japan)

IGRAs for TB infection detection

- QIAReach QuantiFERON-TB (Qiagen, US)

Technologies Endorsed by WHO

Molecular detection of TB disease and/or drug resistance

- Xpert MTB/RIF, MTB/RIF Ultra, and MTB/XDR (Cepheid, US)
- GenoType MTBDRplus and GenoType MTBDRsl (Hain Lifescience/Bruker, Germany)
- Genoscholar NTM+MDRTB II (Nipro, Japan)

IGRAs for TB infection detection

- T-SPOT.TB (Oxford Immunotec, UK)
- QuantiFERON-TB Gold Plus (QFT-Plus) (Qiagen, US)
- Wantai TB-IGRA (Wantai, China)

Technologies in Development

Molecular detection of TB disease and drug resistance detection

- Gendrive MTB/RIF ID (Epistem, UK)
- TruDiagnosis (Akonni, US)
- INFINITIMTB Assay (AutoGenomics, US)
- FluoroType XDR-TB assay (Hain Lifescience, Germany)

Aerosol capture technologies for TB disease detection

- Face Mask Sampling (University of Leicester/FIND/42T, UK)
- AveloCollect (Avelo, Switzerland)

IGRAs for TB infection detection

- IP-10 IGRA Elisa/lateral flow, rBioPharm, Germany
- ichroma™ IGRA-TB, (Boditech Med, South Korea)
- T-Track(R) TB (Lophius Biosciences GmbH, Germany)

Right from understanding key issues to advising you through the right set of insights and recommendations, Aranca provides research, consolidation, and insightful analysis to aid in-depth understanding of therapy and effective decision-making.

01 **Epidemiological Analysis:** Prevalence and diagnosis of diseases based on geography, gender, race and ethnicity, etc.

02 **Diagnosis and Treatment Paradigm:** Analysis of diagnosis and treatment algorithm adopted in clinical practice

03 **Current and Future Landscape:** Current treatments and the latest pipeline landscape assessment for a particular therapy area

04 **Patient Journey Analysis:** Patient flow through different phases of diagnosis and treatment with physician perspective

05 **Humanistic, Economic Burden:** Impact of disease on the patient's mental and economic well-being

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