



WHO/TDR TB Strain Bank

New diagnostics tests for tuberculosis (TB) suitable for low-income settings are urgently needed. This includes tests for the detection of drug resistance which are of ever increasing importance as national TB programs address the challenges of multi-drug resistant TB (MDR-TB) and extensively-drug resistant TB (XDR-TB). In parallel with efforts to develop new tools, more and more disease endemic countries are building capacity to adopt technically challenging, traditional methods for detecting drug resistance. Traditional and new methods will each require implementation of rigorous internal and external quality management practices, to ensure quality results.

An important obstacle to the development of new diagnostic tests for TB and the achievement of quality test results is the lack of access to reference materials. The WHO/TDR TB Strain Bank addresses this need by providing academic and commercial test developers and laboratory managers with a geographically diverse collection of 236 TB isolates comprising all possible combinations of phenotypic resistance to the 4 major anti-tuberculosis drugs i.e. isoniazid, rifampicin, ethambutol with accompanying streptomycin and accompanying detailed genotypic profiling for each strain. Nine laboratories (1) generously contributed strains from their own collections. Together strains originated from 31 countries are included in the WHO/TDR bank.

The strain bank is intended to:

- Promote the development of novel technologies for drug susceptibility testing (DST) appropriate for use in disease endemic countries;
- Facilitate the laboratory evaluation of new (and existing) DST methods ;
- Provide reference materials to support quality control and quality assessment programs for mycobacteria identification and drug susceptibility methods around the world
- Facilitate research that contributes to our basic understanding of global TB epidemiology and evolutionary TB biology

What type of material can be requested?

- Catalogue of 236 reference strains or heat inactivated suspensions accompanied by phenotypic and genotypic profiles

Reference strains are obtained from a single colony according to a strict protocol, the characterization algorithms are available for consultation (2) Strains are confirmed as *Mycobacterium tuberculosis* using biochemical methods, and drug susceptibility testing by proportion method on Lowenstein-Jensen medium follows. 4 to 5 different concentrations of each of the standard 4 drugs were used to assess drug susceptibility (mean inhibitory concentration; MIC).

Subcultures of all strains (drug susceptible and drug resistant) undergo gene sequencing of drug resistance gene regions (*rpoB*, *katG*, *inhA*, *sprL*, 16S-530 loop, 16S-915 region, *embB*) and MIRU-VNTR (Mycobacterial Interspersed Repetitive Units-Variable Number of Tandem Repeats) typing, for strain identification, measures variability in 12 loci: 2,4, 10, 16,20, 23, 24, 26, 27, 31, 39, 40.

Catalogue of strains and heat-inactivated suspensions is available for consultation at:

- Catalogue of available strains and heat inactivated suspensions

Who can request strains?

Strains are available at low cost to scientists and diagnostic test developers (academic and commercial) working towards the development of TB diagnostics suitable for low-income settings and to qualified laboratory personnel for quality control purposes

Who approves the request?

A committee of nine experts in the fields of diagnostic test development, molecular TB epidemiology, mycobacteriology and laboratory management and public health review and approve or reject applications from requesting parties on the basis of scientific or technical merit and compliance with appropriate bio safety practices.

Strains are approved for release either:

- individually
- or as a panel of the complete strain collection (236 strains).

Release of individual strains will principally serve proof-of-concept studies or phylogeny research. Release of the entire bank collection of strains will be intended for evaluation of tests already showing promise and to support the performance of comparative laboratory evaluations of existing diagnostics.

What does it cost?

End-users pay a handling fee per strain and all shipping and import permit expenses. Please contact WHO/TDR for an up to date price list.

How to request strain material?

The Material Transfer Agreement form is available for download:

- Template Request Form and Material Transfer Agreement (word version)
- Template Request Form and Material Transfer Agreement (pdf version)

Minimal information to be disclosed will specify type of assay, technical platform and preliminary data. ANY DATA DISCLOSED will be treated as CONFIDENTIAL information by the TDR TB Bank manager and the Review Committee.

Further information

For additional information, please contact [InfoSpecimen](#)

References

1. List of contributing laboratories
2. Algorithms for phenotypic and genotypic characterization of TB strains