

FIND and WHO/TDR TB Specimen Banks

FIND and WHO/TDR have joined forces to expand access to critical clinical reference materials to drive the development of diagnostics for tuberculosis.

Academic and industry groups working on developing tests for tuberculosis are often stymied by the lack of specimens needed for product development and validation. FIND and WHO/TDR specimen banks address this need by providing an invaluable, growing resource of well-characterized clinical materials for use by academic and commercial test developers.

FIND and WHO/TDR repositories contain samples from symptomatic respiratory patients with and without TB, collected from over a dozen geographically diverse countries.

Aliquots of sputum, serum, plasma, saliva and urine are frozen on site, and maintained at central distribution sites at -70 °C. Each sample is linked to detailed clinical and microbiological information and a final diagnosis is assigned according to a standardized classification scheme.

This initiative is intended to stimulate commercial activity to develop new TB diagnostics, assist in quality control, limit the need for expensive field trials, facilitate approval processes, and simplify direct comparison of new and existing diagnostic kits.

Aliquots from both FIND and WHO/TDR collections are now available upon request through FIND for commercial and academic researchers working towards the development of TB diagnostics.

What types of samples are available?

Sputum - 0.5 ml aliquots

Serum - 0.5 ml aliquots

Plasma (EDTA) - 0.5 ml aliquots

Plasma (P800) - 0.5 ml aliquots

Saliva - 0.5 ml aliquots

Urine - 1.5ml or 3.5ml aliquots

How are samples collected and stored?

Specimens are collected from adult individuals presenting to participating clinics with symptoms of pulmonary TB. All samples are collected before the subject starts any form of TB treatment. Basic processing information for each samples type is outlined below:

SAMPLE TYPE	PROCESSING
Serum and plasma	Centrifugation
Urine	Sedimentation
Sputum	Homogenization with H ₂ O or NALC/Na Citrate and glass beads

All samples are aliquoted in pre-labelled cryotubes and frozen on site before being shipped to one of the central repositories.

Who can request specimens?

Samples are available by application to commercial and academic researchers working towards the development of TB diagnostics suitable for low and middle-income settings.

How to request specimens?

Requests should be made using the Material Request Form available here [word doc. Link] and emailed to specimens@finddiagnostics.org

How will the request be evaluated?

The first priority for this project is to assist in the development or evaluation of existing or emerging diagnostic tools that are considered promising for improving the diagnosis of TB in low and middle-income countries. A Specimen Bank Review Committee (SBRC) composed of five qualified members involved in diagnostics development and TB control will review and approve or reject applications from requesting parties.

Requests which address the following will be given the highest priority:

- Relevance to public health (feasibility and impact on patients and disease control programmes);
- Applicability of the technology in high burden countries;
- Low cost of final product;
- Previous data or scientific evidence supporting the request.

What is expected by the applicants?

All applicants are required to sign a Material Transfer Agreement (MTA) and to forward an electronic copy to FIND. Sample shipment is dependent on a valid, fully executed MTA.

How many samples can be requested?

The adequacy of the request will be evaluated by the SBRC. Sample numbers should be requested based on real needs to achieve the objectives described in the MRF. In the following cases, a more detailed workplan and supporting proof-of-principle data might be required by the SBRC on a case by case basis:

- large sample requests;
- significant scarce diagnostic groups or samples types;
- repeated requests for the same project.

How will the samples be selected?

After approving the request, the following criteria will be considered for sample selection:

- Whenever possible, all samples in a request will be shipped from one repository in order to minimize logistics, shipping costs and time;
- Samples will be shipped from the closest repository;
- To take the best advantage of all collections, samples will be selected on a first-in first- out basis, unless a case is made by the requestor to use the most recently collected samples.

What does it cost?

Applicants are expected to cover handling fees and shipment costs, unless otherwise agreed with FIND. Handling fee is \$20 per aliquot. Indicative shipment cost for 100 aliquots is \$ 2,000.

Where will the samples be shipped from?

Samples are currently stored at three central repositories located in Thailand, France and the US. Please note that import permits are required by most countries to receive sample shipments.

How long does it take?

MRF review by SBRC committee	up to 2 weeks from submission
Export permit application	up to 4 weeks
Sample preparation	up to 4 days, depending on shipment size
Transit time	up to 5 days, depending on distance and customs regulations in receiving country

Please note that the timelines above are indicative and they might change due to circumstances.

Transparency of use

A report summarizing the number of requests received, approved or rejected and the number and type of aliquots distributed will be made available on this website on an annual basis.

Further information

For additional information, please contact specimens@finddiagnostics.org