

### About the specimen bank

FIND manages a bank of well-characterized tuberculosis specimens for IVD manufacturers and academic researchers working on the development of TB diagnostics. By providing access to TB specimens from FIND and WHO collections, we support the consented development and evaluation of new and existing tools to improve TB diagnosis.

Specimens are collected at participating clinics from consenting adults with symptoms of pulmonary tuberculosis. FIND follows good clinical and laboratory practice in sample handling. The samples are stored in central repositories in France and the U.S. and are shipped to researchers upon request. The requests are screened by a Sample Bank Review Committee based on scientific merits and value to the global health community.

#### Aliquot types

- Sputum: 0.5 ml
- Serum: 0.5 ml
- Plasma (EDTA): 0.5 ml
- Plasma (P800): 0.5 ml
- Saliva: 0.5 ml
- Urine: 1.5ml or 3.5ml

### Distribution of specimens

In 2014, FIND TB Specimen Bank dispatched 25 shipments to 20 different test developers for a total of 5,331 aliquots. In Q1 and Q2 of 2015, FIND TB Specimen Bank dispatched 15 shipments to test developers totaling 4,408 aliquots. This steep increase in the number of requests reflects the growing need for well characterized specimens among diagnostic developers. See reverse for details.

### Inventory

FIND repository is currently holding 49,593 aliquots from 3,694 patients. Collection is ongoing and patients for whom data entry is in progress or whose samples are still at the collection sites, are not included. FIND's repository includes aliquots from Bangladesh, Brazil, Peru, South Africa, Uganda, and Vietnam.

In addition to its own collection, FIND also manages the WHO-TDR TB collection, which includes over 28,000 aliquots from Spain, Gambia, Salvador, South Africa, Tanzania, Uganda, Vietnam, Canada, Bangladesh, Brazil, Colombia, Kenya

### Summary aliquot inventory at FIND repository by country

Country	Patients	Total
Bangladesh	91	1,128
Brazil	176	176
Peru	886	10,913
South Africa	515	3,710
Uganda	256	2,114
Viet Nam	1,770	31,552
<b>Total</b>	<b>3,694</b>	<b>49,593</b>

### Summary inventory of aliquots by diagnostic category as of June 2015

*WHO-TDR collection at ZeptoMetrix, USA*

Diagnostic category	Patients	Sputum	Serum	Urine	Total
Smear-pos, cult-pos (WHO Cat.1)	688	930	10,403	1,028	12,361
Smear-neg, cult-pos (WHO Cat.2)	90	190	1,396	197	1,783
Smear-neg, cult-neg, CXR-pos (WHO Cat.3)	66	163	1,122	163	1,448
Non TB 4 (WHO Cat.4)	146	9	1,904	161	2,074
<b>Total</b>	<b>990</b>	<b>1,292</b>	<b>14,825</b>	<b>1,549</b>	<b>17,666</b>

*WHO-TDR collection at Biobanque de Picardie, FR*

Diagnostic Category	Patients	Sputum	Serum	Urine	Saliva	Total
Smear-pos, cult-pos (WHO Cat.1)	602	671	3360	439	677	5,210
Smear-neg, cult-pos (WHO Cat.2)	62	9	387	78	66	543
Smear-neg, cult-neg, CXR-pos (WHO Cat.3)	24	13	55	29	24	125
Non TB 4 (WHO Cat.4)	498	1,337	1,487	1,734	104	4,670
<b>Total</b>	<b>1,186</b>	<b>2,030</b>	<b>5,289</b>	<b>2,280</b>	<b>871</b>	<b>10,548</b>

*FIND collection at ZeptoMetrix, USA*

Diagnostic category	Patients	Sputum	Serum	Urine	P800	Plasma	Total
Latent TB	154	0	915	0	0	1,285	2,200
Non TB	836	1287	4,690	591	394	2,681	9,643
Smear-neg, cult-neg, CXR-pos	10	15	27	27	32	51	152
Smear-neg, cult-pos	783	2,150	5,673	1,932	626	1,348	11,729
Smear-pos, cult-pos	1,911	6,827	11,553	4,005	1,449	2,035	25,869
<b>Total</b>	<b>3,694</b>	<b>10,279</b>	<b>22,858</b>	<b>6,555</b>	<b>2,501</b>	<b>3,472</b>	<b>49,593</b>

### New drug-resistant collection

In response to increasing demand, FIND expanded the specimen collection to include specimens and strains from TB drug-resistant patients. Drug-resistant samples are collected in Georgia, Moldova, KwaZulu-Natal in South Africa, Viet Nam and Peru.

### Survey on specimen bank

In early 2015, FIND conducted a survey about the specimen bank among TB researchers to find out what they thought of the service, what improvements could be made and what types of TB samples and strains would be most useful in their work. Among those surveyed, 82% had used the FIND TB specimen bank and of those, 94% were satisfied or extremely satisfied with the service provided. Based on respondent feedback, FIND will increase availability of HIV-positive and latent TB samples, as well as poly-resistant TB strains.

### Improved quality of specimens

To improve quality and ensure high standards, in 2015 FIND implemented additional quality control and quality assurance processes for blood, sputum, and urine samples. New processes include recording critical data about the collection, conducting additional baseline testing, and applying stringent monitoring of storage conditions and processing times. For instance, now baseline testing of urine samples with dipsticks is allowing documentation of the physical characteristics of the sample and presence of proteins, glucose, ketones, haemoglobin, bilirubin, urobilinogen, acetone, nitrite and leucocytes.

## 2014–Q2 2015 requests approved & specimen distributed

Organization	Total number of aliquots requested & type	Purpose	Total number of aliquots granted & type	Collection
BMGF - Colorado State University,	324 sera	BMGF TB Biomarker discovery project	324 sera	FIND
Rutgers New Jersey Medical School, USA	56 sputa	Xpert <sup>®</sup> MTB/RIF Ultra development	56 sputa	FIND
Transmembrane Biosciences, USA	200 sera	Evaluation of TB serological assay prototype	195 sera	FIND
ProteinLogic Ltd, UK	300 sera	Identification of Biomarkers in Active TB	300 sera	FIND
Tangen Biosciences, USA	75 sputa	Evaluation of Tangen TB assay and sputum processing	149 sputa	FIND
Wayne State University, USA	200 sera	Immunoscreening of a library with sera of TB patients to identify TB biomarkers	150 sera	FIND
BMGF - Colorado State University, USA	320 sera	BMGF TB Biomarker discovery project	320 sera	FIND & WHO-TDR
Rutgers New Jersey Medical School, USA	294 sputa	Xpert <sup>®</sup> MTB/RIF Ultra development	294 sputa	FIND
Global BioDiagnostics, USA	600 sputa	Detection of beta-Lactamase C in sputa	250 sputa	FIND
Rutgers New Jersey Medical School, USA	200 sputa	Epistem LOD study	200 sputa	FIND
Natural and Medical Science Institute, DE	30 sera	TB assay development based on IgA detection	30 sera	FIND
Standard Diagnostics, KOR	800 sputa	TB assay development based on LAM	800 sputa	FIND
Bangor University, UK	1440 sera, plasma	Validation of a new screening test for TB	200 sera	FIND
Ecole Polytechnique Fédérale de Lausanne (EPFL), CH	30 sputa	TB biomarker discovery project: metagenomics studies of the flora of TB patients.	30 sputa	FIND
Becton Dickinson and Company, USA	100 sputa	Development of automated smear microscopy system	100 sputa	FIND
Global BioDiagnostics, USA	320 sera, sputa, urine	Detection of beta-Lactamase C in sputa	310 sera, sputa, urine	FIND
Chembio Diagnostic Systems, USA	200 sera	Evaluation of new serological test	200 sera	FIND
Ragon Institute, USA	80 sera or plasma	Characterization of TB-specific IgG through capillary electrophoretic technique to discriminate between active and latent TB	80 sera	FIND
Natural and Medical Science Institute, DE	20 sera	Development of a dimeric IgA assay for TB	20 sera	FIND
Abbott Laboratories, USA	400 sputa	To test the performance of Abbot prototype RealTime MTB detection assay	300 sputa	FIND
IDRI, USA	10 urine	To assess specificity of two ELISA tests for Leishmania	10 urine	WHO-TDR
Lionex, DE	900 sera, sputa, urine	Evaluation of rapid antibody and antigen detection TB tests, including LAM in urine.	633 sera, sputa, urine	WHO-TDR
Rush University, USA	50 sputa	Validation of novel TB DNA detection method	50 sputa	WHO-TDR
Seattle Biomed, USA	30 sputa	Development of novel sputum processing method	30 sputa	WHO-TDR
University of Minnesota, USA	900 sera, urine	Validation of a mycobacterial peptide panel	300 sera	WHO-TDR
Somalogic, USA	760 sera, urine	BMGF TB Biomarker Discovery Project	749 sera, urine	FIND & WHO-TDR
John Hopkins University, USA	200 saliva, sputum, urine, plasma	Development of microchip-based platform	120 saliva, sputum	FIND & WHO-TDR
ARUP Labs, USA	30 sputa	Validation of RT PCR test for TB	30 sputa	FIND
Standard Diagnostics, KOR	400 sputa	Development of LAM-based TB test	400 sputa	FIND
Roche Diagnostics, CH	2850 sputa	Development of MTB tests on the COBAS <sup>®</sup> platform	1155 sputa	FIND
Jei Daniel Biotech Corp., TWN	200 sputa	Evaluation of MTB antigen rapid test	200 sputa	FIND
Becton Dickinson, USA	355 sputa	Development of a new molecular test for MDR-TB	210 sputa	FIND
Colorado State University, USA	480 sera	BMGF TB Biomarker Discovery Project	476 sera	FIND
MesoScale Diagnostics, USA	15 urine	Development of MTB LAM-based test	15 urine	FIND
TB Biosciences, USA	75 sera	Development of point-of-care TB test	75 sera	FIND
Hema Diagnostics, USA	250 sera	Evaluation of a rapid test for TB	80 sera	FIND
Tufts University, USA	225 serum, sputum, urine	Development of a molecular array assay for TB	225 serum, sputum, urine	FIND
ProteinLogic, UK	300 sera	Evaluation of a new TB detection method	300 sera	FIND
Northwestern University CIGHT, USA	400 sputa	Development of a MTB screening assay	188 sputa	FIND
Global Good, USA	520 serum, sputum, urine	Feasibility study for improved smear microscopy and new TB assay development	185 serum, sputum, urine	FIND