

## Q3 2015 - Q3 2016 ACTIVITY REPORT & UPDATES



### About the specimen bank

FIND manages an open-access collection of well-characterized specimens from tuberculosis patients from different geographic locations that are then made available to IVD manufacturers and academic researchers working on the development of TB diagnostics. By providing high quality clinical samples 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.

### Distribution of specimens

The FIND TB Specimen Bank dispatched 19 shipments to 14 different test developers in Q3-Q4 of 2015 and 14 shipments to 12 test developers in Q1-Q3 2016. A total number of 5,253 aliquots were granted. *See reverse for details.*

#### Summary of requests and aliquots granted

Period	Requests approved	# of requestors	Sputum	Serum	Plasma	P800	Urine	Total
Q3-Q4 2015	12	11	250	725	60	0	595	1,630
Q1-Q3 2016	23	20	1,043	1,356	2	303	919	3,623
<b>Total</b>	<b>35</b>	<b>31</b>	<b>1,293</b>	<b>2,081</b>	<b>62</b>	<b>303</b>	<b>1,514</b>	<b>5,253</b>

### Inventory

The FIND repository currently holds 48,452 aliquots from collection sites in Bangladesh, Brazil, Georgia, Moldova, Peru, South Africa, Uganda, Vietnam. In addition to its own collection, FIND also manages the WHO-TDR TB collection, which includes 27,570 aliquots from Spain, Gambia, Salvador, South Africa, Tanzania, Uganda, Vietnam, Canada, Bangladesh, Brazil, Colombia, Kenya.

### New collections

In 2014, FIND started collecting specimens from patients with multidrug-resistant TB. The collection contains sputum, urine, blood and matched strains from patients in Georgia, Moldova, Peru, South Africa and will soon add specimens from Vietnam. FIND is also collecting blood, urine and sputum specimens from TB patients at baseline and different time points during their treatment in order to develop a treatment monitoring collection. Treatment monitoring specimens are being collected in Peru, Moldova, South Africa and collection is about to start in Vietnam.

Since 2015, FIND has collected, characterized and manufactured a number of TB strains that are searchable through a virtual strain bank (VSB). By October 2017, there should be approximately 1000 isolates. Researchers whose labs house well-characterized strains are being encouraged to further populate the VSB with data concerning their isolates. The VSB will provide a searchable portal and will facilitate further collaboration among TB researchers and developers.

### Summary inventory as of October 2016

#### FIND collection at ZeptoMetrix, USA

Diagnostic category	Patients	Sputum	Serum	Plasma	P800	Urine	Total
Latent TB	154	0	800	1,285	0	0	2,085
Non TB	834	720	4,168	1,026	833	459	7,206
Likely subclinical TB	1	0	8	0	0	0	8
Smear-neg, cult-neg, CXR-pos	13	12	41	51	86	57	247
Smear-neg, cult-pos	811	1,686	6,563	807	994	2,157	12,207
Smear-pos, cult-pos	1,917	5,891	13,810	1,831	1,738	3,429	26,699
<b>Total</b>	<b>3,730</b>	<b>8,309</b>	<b>25,390</b>	<b>5,000</b>	<b>3,651</b>	<b>6,102</b>	<b>48,452</b>

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

Diagnostic category	Patients	Sputum	Serum	Urine	Total
Smear-pos, cult-pos (WHO Cat.1)	690	748	10,318	688	11,754
Smear-neg, cult-pos (WHO Cat.2)	92	190	1,410	203	1,803
Smear-neg, cult-neg, CXR-pos (WHO Cat.3)	66	163	1,124	163	1,450
Non-TB (WHO Cat.4)	148	8	1,920	166	2,094
<b>Total</b>	<b>996</b>	<b>1,109</b>	<b>14,772</b>	<b>1,220</b>	<b>17,101</b>

#### WHO-TDR collection at ZeptoMetrix, USA

Diagnostic category	Patients	Sputum	Serum	Urine	Saliva	Total
Smear-pos, cult-pos (WHO Cat.1)	602	671	3,359	439	677	5,146
Smear-neg, cult-pos (WHO Cat.2)	62	9	387	78	66	540
Smear-neg, cult-neg, CXR-pos (WHO Cat.3)	24	13	55	29	24	121
Non-TB (WHO Cat.4)	498	1,337	1,487	1,734	104	4,662
<b>Total</b>	<b>1,186</b>	<b>2,030</b>	<b>5,288</b>	<b>2,280</b>	<b>871</b>	<b>10,469</b>

#### Summary inventory by selected countries Aliquot types

Country	Patients	Total aliquots	Serum	Urine
Bangladesh	88	1,057	0.5 ml	0.5 ml
Brazil	185	185	0.5 ml	0.5 ml
Peru	814	8,877	0.5 ml	0.5 ml
South Africa	682	8,884	0.5 ml	0.5 ml
Uganda	256	2,115	0.5 ml	0.5 ml
Viet Nam	1,725	27,334	1.5ml or 3.5ml	

The VSB has strict governance policies, and data contributors always maintain control over their strains.

### Quality control

Biomolecular integrity of collected specimens is of utmost importance to avoid pre-analytical bias that can compromise study results. To ensure that specimens are handled correctly at the collection sites FIND has implemented additional Quality Control Case Report Forms that are used to document critical pre-analytical steps, including delay between collection and processing, centrifugation conditions, transport conditions, storage duration and temperature.

FIND is also spearheading quality control for TB samples through regular retesting of sample subsets to assess viability of MTB, purity and biomolecular integrity to ensure highest quality of the biorepository.

### Follow-up on distributed specimens

FIND encourages researchers to report back the data obtained using FIND specimens and to make this data available to the scientific community. Data sharing is important for information aggregation and new knowledge creation. FIND will also use the data to perform an additional quality check of its specimens.

## Q3 2015 – Q3 2016 requests approved & specimens distributed

Organization	Aliquots requested	Purpose	Aliquots granted
Lincoln Memorial University	60 sputa	Lipidomics analysis of TB specimens and comparison to non-TB	58 sputa
	60 plasma		60 plasma
Queen's University	5 sera	Development of an assay to differentiate <i>M. bovis</i> and <i>M. tuberculosis</i>	5 sera
	5 urine		5 urine
Weil Medical College of Cornell University	200 urine	Identification of urine biomarkers of TB	100 urine
Meso Scale Diagnostics, USA	60 sera	Identification and validation of new TB biomarkers	60 sera
	120 urine		120 urine
University of Michigan	80 sera	Identification of TB biomarkers	80 sera
BMGF - Colorado State University, USA	180 sera	BMGF TB Biomarker discovery project	180 sera
Roche Diagnostics International AG	90 sputa	Validation of NAAT test for detection of TB MDR	90 sputa
BMGF – Institute for Systems Biology	149 P800 plasma	BMGF TB biomarker discovery project	149 P800 plasma
	191 35 ml urine		191 35 ml urine
Global Good	200 urine	Validation of LFA-based assay detecting TB biomarker (LAM)	136 urine
BMGF - Colorado State University, USA	200 sera	BMGF TB Biomarker discovery project	200 sera
	200 urine		200 urine
CSIR – Institute of Microbial Technology	100 sera	Validation of TB biomarker	80 sera
	100 sputa		80 sputa
Imhoteq LLC/Kestrel BioSciences, USA	240 sputa	Validation of a new LFA for TB	100 sputa
Hain Lifesciences, Germany	100 sputa	Evaluation of FluoroType MTBDR assay	100 sputa
Tufts University, USA	200 sera	TB biomarker evaluation	200 sera
TB Biosciences, USA	200 sera	TB biomarker evaluation	200 sera
Ceres Nanosciences, USA	24 urine	Feasibility study for LFA LAM test	34 urine
Otsuka Pharmaceutical Co., Japan	250 sputa	ELISA test to detect LAM in sputum	250 sputa
Broad Institute of MIT and Harvard, USA	600 sera/plasma	Validation of TB biomarkers	270 sera
			50 plasma
BMGF – Institute for Systems Biology	155 P800 plasma	BMGF TB biomarker discovery project	155 P800 plasma
	155 urine		155 urine
Wave Guide Corporation	30 sera	Validation of NMR-based TB diagnostic tool	27 sera
	30 sputa		27 sputa
All India Institute, India	120 sera	Antibody detection assay for TB diagnosis	80 sera
Somalogic Inc., USA	2 sera	TB biomarkers discovery	2 plasma
			1 serum
The Forsyth Institute	100 sera	Validation of serological TB biomarkers	60 sera
Epistem Ltd., UK	200 sputa	Validation of MTB/RIF assay	20 sputa
BMGF - Colorado State University, USA	300 urine	BMGF TB Biomarker discovery project	300 sera
Meso Scale Diagnostics, USA	60 sera	Identification and validation of new TB biomarkers	60 sera
	120 urine		120 urine
ProteinLogic Ltd., USA	1600 sera	Validation of identified TB biomarkers	300 sera
The Forsyth Institute	45 sera	Validation of serological TB biomarkers	45 sera
Cepheid, USA	224 sputa	Evaluation of Xpert MTB/RIF Ultra assay	256 sputa
Fujifilm Corporation, Japan	119 urine	Development of LAM assay	119 urine
Northwestern University, USA	300 sputa	Development of TB screening assay	300 sputa
BD Diagnostics, USA	275 sputa	Evaluation of MDR TB test	275 sputa
Rutgers University, USA	148 sera	Detection of LAM in non-sputum samples	148 sera
	59 urine		59 urine
	100 P800 plasma 50 PBMC		Pending: 100 P800 plasma and 50 PBMC