DECENTRALIZATION OF TB TESTING IS CRITICAL FOR EQUITABLE ACCESS TO DIAGNOSIS & CARE

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RELEVANT FINANCIAL RELATIONSHIPS

Cassandra Kelly-Cirino is an employee of FIND, a not-for-profit foundation that supports the evaluation of publicly prioritized TB assays and the implementation of WHO-approved (guidance and prequalification) assays using donor grants.

FIND has product evaluation agreements with several private sector companies that design diagnostics for TB and other diseases.

These agreements strictly define FIND’s independence and neutrality with regard to these private sector companies.
FIND SEEKS TO ENSURE EQUITABLE ACCESS TO RELIABLE DIAGNOSIS AROUND THE WORLD

We connect countries and communities, funders, decisionmakers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems.

- Established in 2003 as a product development & delivery partnership
- Co-convener of the Access to COVID-19 Tools (ACT) Accelerator Diagnostic Pillar
- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member

TB IS THE 2nd LEADING INFECTIOUS KILLER IN THE WORLD AFTER COVID-19
TESTING REMAINS THE WEAKEST LINK IN THE CARE CASCADE

38% of TB cases remained undiagnosed globally in 2021, preventing 4 million people from accessing treatment and allowing the disease to spread1

- Only 1 in 5 people with TB are bacterially confirmed
- Only 1 in 3 people with drug-resistant TB are tested
- 1.1M new infections and 250k deaths are reported among children every year

Existing diagnostic tools are not fit-for-purpose nor available where they are needed most

- 70% of patients seek care at the community and primary care levels where there is no capacity to diagnose TB
- Symptom-screening misses 50% of TB cases in communities1
- Reliance on sputum-based tests makes diagnosis difficult and selects patients with advanced disease

1Pai M et al, Nat. Microb. 2017
2WHO global TB report 2022
EXPANDING ACCESS TO TB DIAGNOSTIC TO
FIND THE MISSING MILLIONS AND LINK THEM TO TREATMENT

Quality, accessible diagnostics suitable for use at all levels of the health systems are urgently needed to reach WHO targets to end TB.

50% reduction in TB incidence rate by 2025

40 million people treated by 2022

FIND STRATEGIC PRIORITIES IN TB

Development and evaluation of non-sputum based rapid tests adaptable and accessible to every setting

Development and evaluation of POC molecular diagnostic platforms for fast and accurate TB detection

New tools for rapid identification and surveillance of drug-resistant TB

Evaluation and validation of AI-based technologies for supporting TB screening results interpretation

Support roll-out of tests to detect and treat latent TB infections

A RAPIDLY EVOLVING TB DIAGNOSTIC PIPELINE


MTB/RIF (GeneXpert; Cepheid)

TB LAM RDT (Alere)

Moderate complexity high-throughput assays (Roche, BD, Hain, Abbott)

TrueNat TB & RIF (Molbio)

ULTRA on 10-color (Cepheid)

RDT IGRAs

POC MDx and new non-sputum samples

2nd/3rd generation LAM

MTB/RIF (first line)

1st line drugs LPA – TB (2nd gen) (Hain Lifescience; NIPRO Corporation)

2nd line drugs LPA – TB (Hain Lifescience)

TB LAMP (Eiken)

MTB/XDR 10 color system (GeneXpert; Cepheid)

Genoscholar

PZA-TB (Nipro)

CAD solutions for CXR interpretation

Targeted sequencing for diagnosis and surveillance

New low complexity NAAT instruments and tests (Bioneer, SD Biosensor...)

Specific skin tests incl Cy-TB

Digital screening tools, cough sounds etc...

...and many others
LACK OF DIAGNOSTICS WHERE PEOPLE SEEK CARE LEADS TO MISSED CASES AND INEQUITY IN DIAGNOSING TB

EQUITABLE ACCESS = BRINGING TESTS CLOSER TO HOME
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- True point-of-care
- Early-stage development
  - 27
- Late-stage development
  - 7
- 123
- Near point-of-care
- 4
- On the market
- 27
- The platforms with the highest demonstrated sensitivity are PCR-based amplification
- 5 of the platforms are disposable

EQUITABLE ACCESS = SIMPLIFIED SAMPLING

- Tongue swabs not sputum
- Step-by-step test instructions on screen
- Digital display of results and reporting
- Data analytics and decision support
- Seamless, secure connectivity to the cloud and health IT systems

Proprietary process subject to LumiraDx IP protection. Project subject to further development and regulatory approval.
### EQUITABLE ACCESS = PRODUCT DIVERSITY

<table>
<thead>
<tr>
<th>Device</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>SD BIOSENSOR, STANDARD M10</strong></td>
<td>- TB, RIF, INH&lt;br&gt;- Result in 80 mins&lt;br&gt;- Clinical trials start 2023</td>
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<tr>
<td><strong>BIONEER, IRON-qPCR</strong></td>
<td>- TB, RIF, INH, FO, SLID&lt;br&gt;- Result in 80 mins&lt;br&gt;- Clinical trials started 2022</td>
</tr>
<tr>
<td><strong>MOLBIO, TRUENAT</strong></td>
<td>- New Ultima, INH and FO chips&lt;br&gt;- Combined TB and Covid-19 assay&lt;br&gt;- Clinical trials started 2022</td>
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<tr>
<td><strong>USTAR</strong></td>
<td>- Two platform, POC and near-POC&lt;br&gt;- TB, (+RIF), result in 45-65 mins&lt;br&gt;- Commercially available in China</td>
</tr>
<tr>
<td><strong>Sansure</strong></td>
<td>- TB, RIF&lt;br&gt;- Result in 30-60 mins&lt;br&gt;- Swab and sputum</td>
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<tr>
<td><strong>MyLAB, compact Dx</strong></td>
<td>- 8 samples per run&lt;br&gt;- Fully automated qPCR with integrated extraction&lt;br&gt;- Commercially available in India</td>
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### EQUITABLE ACCESS = MANUFACTURING WHERE IT IS NEEDED

To support the COVID response, FIND and Unitaid partnered to accelerate the availability and affordability of quality-assured Ag RDTs for SARS-CoV-2 in LMICs through local manufacturing.

- **Funding** to support capacity expansion in exchange for access pricing and volume
- **Technical assistance** for manufacturing tech, regulatory & market entry
- **Technology transfer partnership matchmaking**

[Map showing manufacturing locations and partner organizations]
GLOBAL PARTNERSHIPS TO ACCELERATE INNOVATIONS IN TB

Major boost to progress in tuberculosis testing on World TB Day as diagnostics partners bring together SMART4TB, DriveDx4TB, FEND-TB and R2D2 TB Network projects

- Collaboration agreement unveiled between SMART4TB, DriveDx4TB, FEND-TB and the R2D2 TB Network, representing the largest-ever coordinated effort to accelerate TB diagnostic development
- Memorandum of understanding signed between FIND and the Johns Hopkins University, with agreements also in place with the University of California San Francisco (UCSF), Rutgers University and Heidelberg University Hospital
- A joint Steering Committee will oversee a coordinating hub with global expertise for the development of key diagnostic technologies in TB, aligned with the goals set out in the UN Resolution on TB from 2018 that will be reviewed at a second High-Level Meeting in September

GENEVA, SWITZERLAND – 24 March 2023. Today, on World TB Day, FIND and partners announced a set of agreements between FIND, Johns Hopkins University, University of California San Francisco (UCSF), Rutgers University and Heidelberg University Hospital that bring together the SMART4TB, DriveDx4TB, FEND-TB and R2D2 TB Network projects to form the largest-ever coordinated effort to accelerate TB diagnostic development.

$80 Million investment in TB Diagnostics

- Includes Adults, Children and Drug-resistant TB
- Spans Early feasibility to Implementation
- Focuses on New Platforms and Sample Types emerging from the COVID-19 accelerated pipeline

EQUITABLE ACCESS IS KEY TO ADDRESSING TB GLOBALLY

- Ensuring people can access testing as close to home as possible is key to closing the diagnosis gap
- Leveraging COVID-19 investments in molecular and RDTs ensures the TB diagnostic pipeline evolves quickly and can be manufactured where needed
- Collaboration across countries and partners is essential to evaluate new technologies, adapt guidelines and ensure rapid uptake of emerging solutions
Thank you to the FIND TB team!

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