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

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1

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RELEVANT FINANCIAL RELATIONSHIPS

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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.

2

2

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-convenor of the Access to COVID-19 Tools (ACT) Accelerator Diagnostic Pillar
- ◆ WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- ◆ WHO SAGE-IVD member

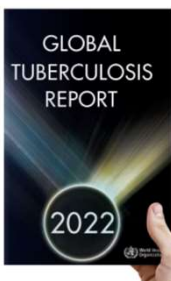


3

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

4

4

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**

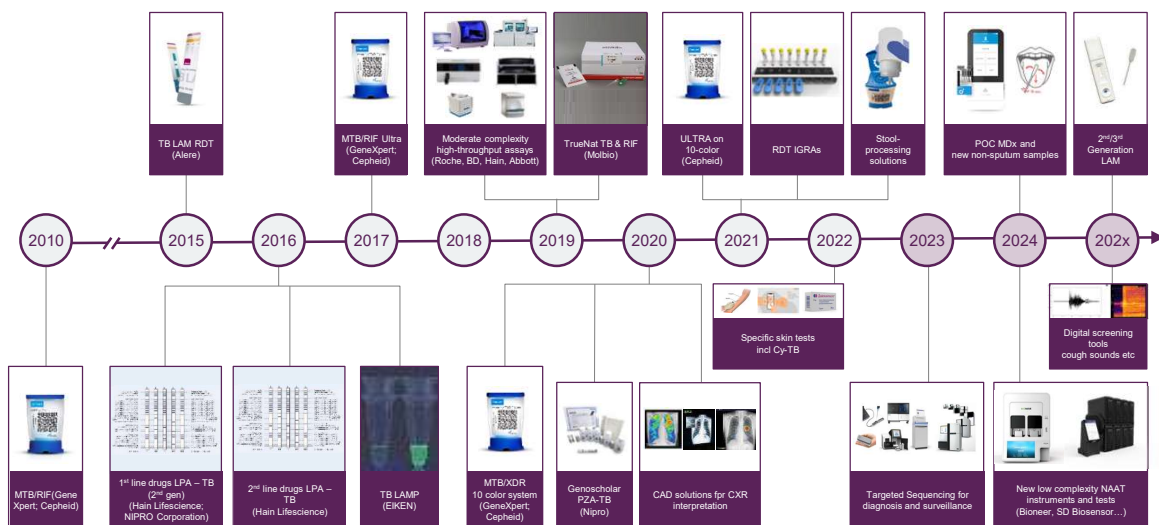
Evaluation and validation of **AI-based technologies** for supporting TB screening results interpretation

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

5

5

A RAPIDLY EVOLVING TB DIAGNOSTIC PIPELINE

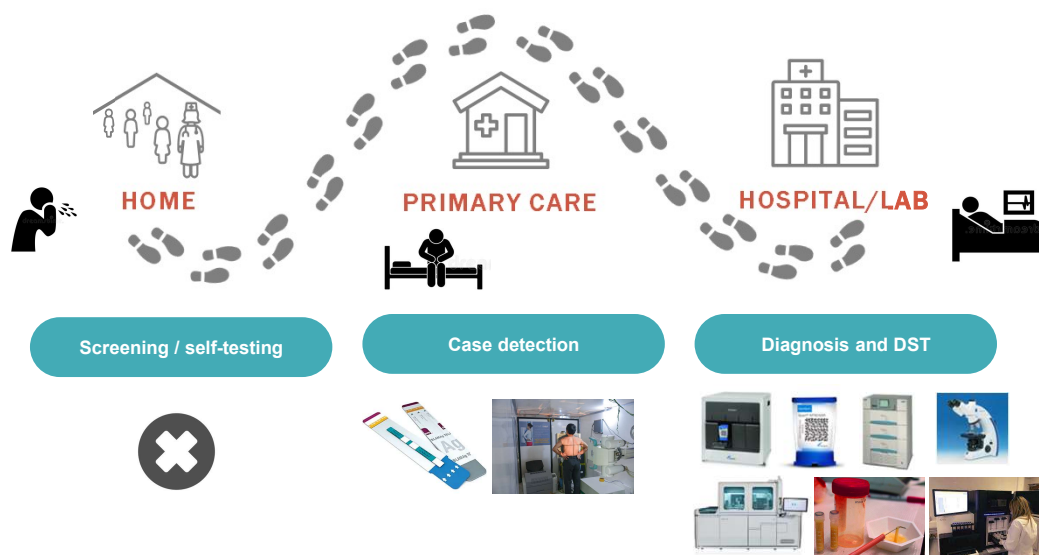


...and many others

6

6

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



7

EQUITABLE ACCESS = BRINGING TESTS CLOSER TO HOME

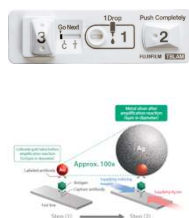


Alere LAM

- Narrow use case but saves lives

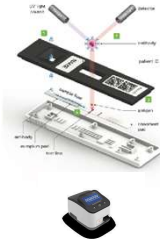


Fujifilm



- Clinical evidence showing better accuracy than Alere TB determine
- Issue with Lot variability
- High cost

SD Biosensor



- Fluorescence based test
- Under development

Boditech



- Fluorescence based test
- Under development

Abbott



- LAM concentration device
- Under development
- Visual readout

Salus



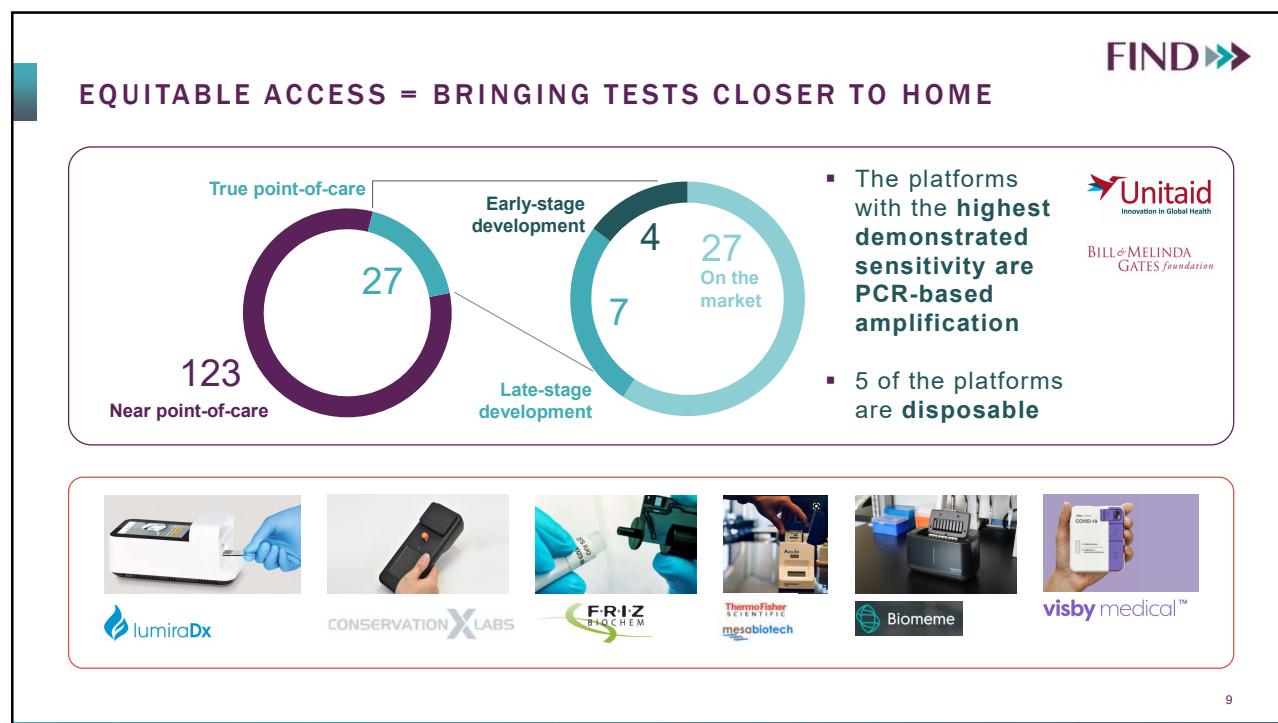
- Integrated sample preparation device
- Under development
- Visual readout

Tests requiring a reader

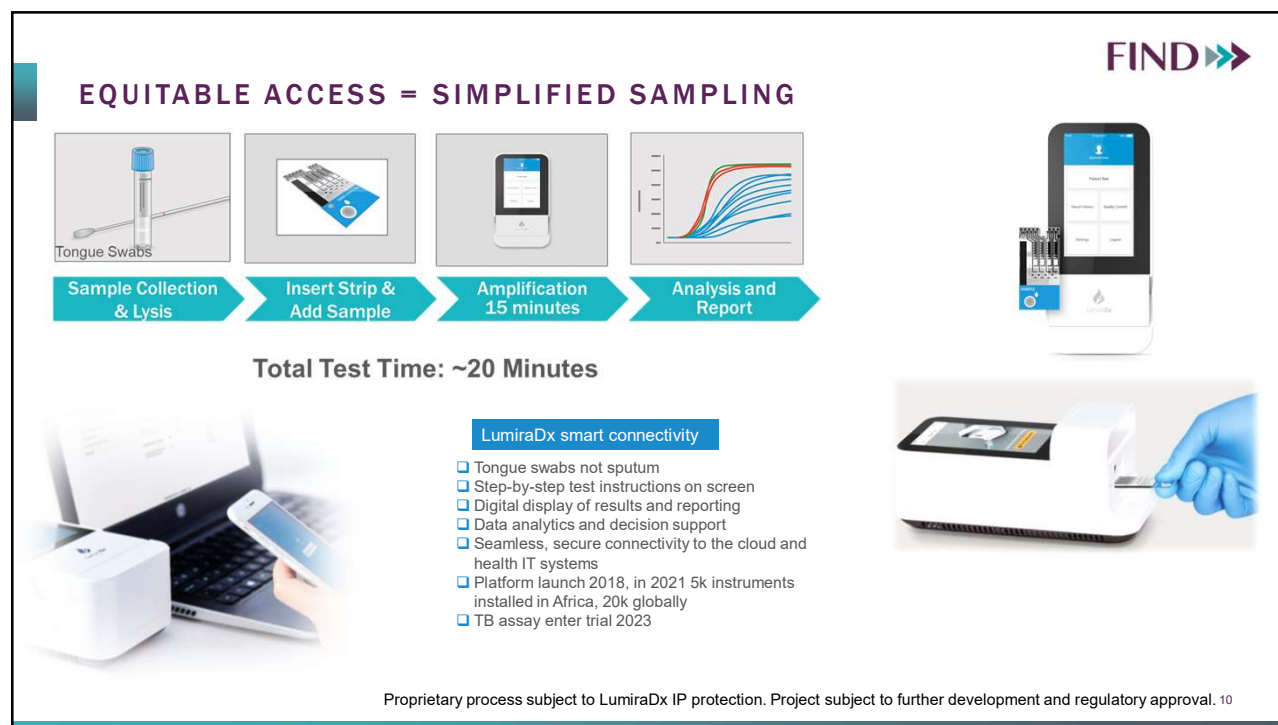
Tests with urine concentration

8

8



9



10

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EQUITABLE ACCESS = PRODUCT DIVERSITY

SD BIOSENSOR, STANDARD M10  STANDARD M10 - TB, RIF, INH - Result in 80 mins - Clinical trials start 2023	BIONEER, IRON-qPCR  - TB, RIF, INH, FQ, SLID - Result in 60 mins - Clinical trials started 2022	MOLBIO, TRUENAT  - New Ultima, INH and FQ chips - Combined TB and Covid-19 assay - Clinical trials started 2022
USTAR  - Two platform, POC and near-POC - TB, (+RIF), result in 45-65 mins - Commercially available in China	Sansure  (smart screen) (Ponatic 4) - TB, RIF - Result in 30-60 mins - Swab and sputum	MyLAB, compact Dx  - 8 samples per run - Fully automated qPCR with integrated extraction - Commercially available in India

11

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Unitaid
Innovation in Global Health

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
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DCN Center of Excellence to facilitate Tech Transfer
Training and transfer COVID-19 Ag RDT
Manufacturing expanded at up to 50 Mio tests/year + Technical assistance

ga DIAGNOSTICS
Training and transfer COVID-19 Ag RDT

BIONOTE
Manufacturing expanded at 144 Mio tests/year + Technical assistance

Wondfo
Manufacturing expanded at 120 Mio tests/year + Technical assistance

Premier Medical Corporation Private Limited
Manufacturing expanded at 120 Mio tests/year + Technical assistance

DIAUROPIX Manufacturing expanded at up to 50 Mio tests/year + Technical assistance

ACTaccelerator
ACCESS TO COVID-19 TOOLS

12

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.



<https://tbcenter.jhu.edu/smart4tb/>



<https://www.finddx.org/>



<https://www.fend-tb.org/>



<https://tb.ucsf.edu/r2d2-tb-network>

\$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

13

13



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

14

14

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15