



TB diagnostic pipeline and opportunities arising from COVID
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Head of TB programme

www.finddx.org

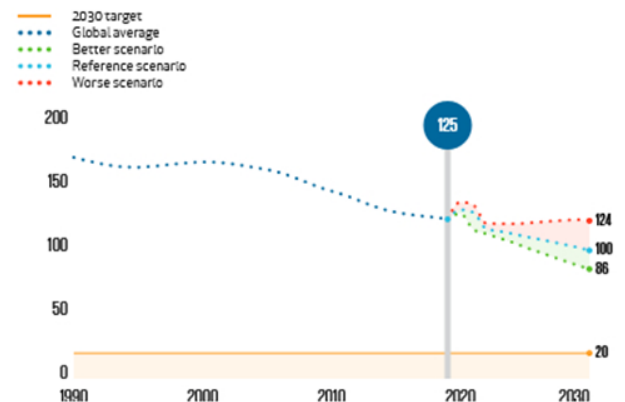
COVID-19 HAS CHANGED THINGS...



GLOBAL PROGRESS AND PROJECTIONS FOR TUBERCULOSIS

SDG target: End the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases.

New cases of tuberculosis per 100,000 people

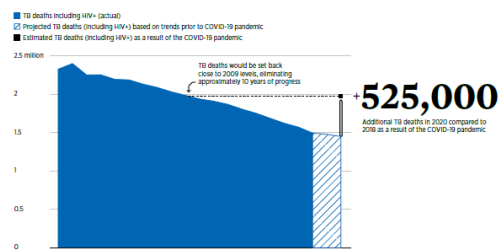


Source: Bill & Melinda Gates Foundation, 2020 Goalkeepers Report. Data from IHME. <http://gates.ly/GK20Tuberculosis>



Tuberculosis deaths: impact of COVID-19

POTENTIAL INCREASE IN TB DEATHS DUE TO TB SERVICE DISRUPTION IN THE CONTEXT OF THE COVID-19 PANDEMIC GLOBALLY



Estimates of TB deaths (including HIV) over 2000–2018 from WHO Global TB Report 2019. Estimation of projected TB deaths over 2018–2030 based on continuation of trends prior to COVID-19. Potential TB deaths (including HIV) globally as a result of the COVID-19 pandemic estimated for the year 2020 from Stop TB Partnership (and partners) modelling study, 2020 which assumed a conservative lockdown period of 2 months and recovery period of 10 months. These additional estimated TB deaths are due to TB service disruptions and exclude TB deaths that may happen in people living with HIV because of disruptions of ARV and other HIV-related services. See http://www.stopsb.org/docs/default-source/who-modelling-report-2020/WHO_TB_COVID19_FINAL.pdf?sfvrsn=1 to learn more.



COVID-19 related disruptions to TB services could lead to

6.3
million
additional people
developing TB

1.4
million
additional
TB deaths

by 2025



IN INDIA

36% OF PEOPLE WITH TB reported health facilities they normally visit closed

*GFIC= Global Fund implementing countries

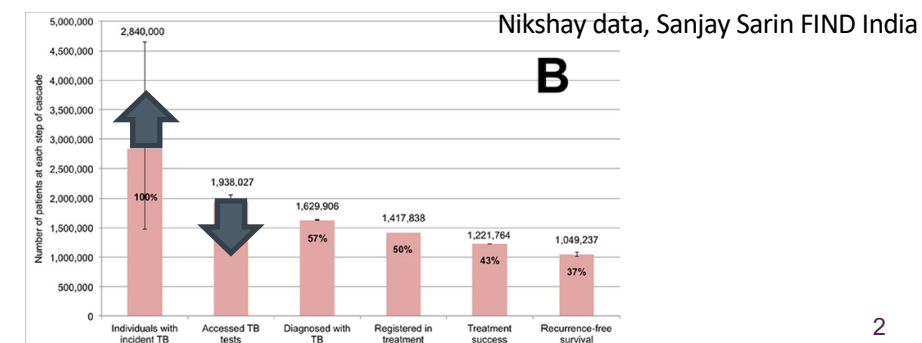
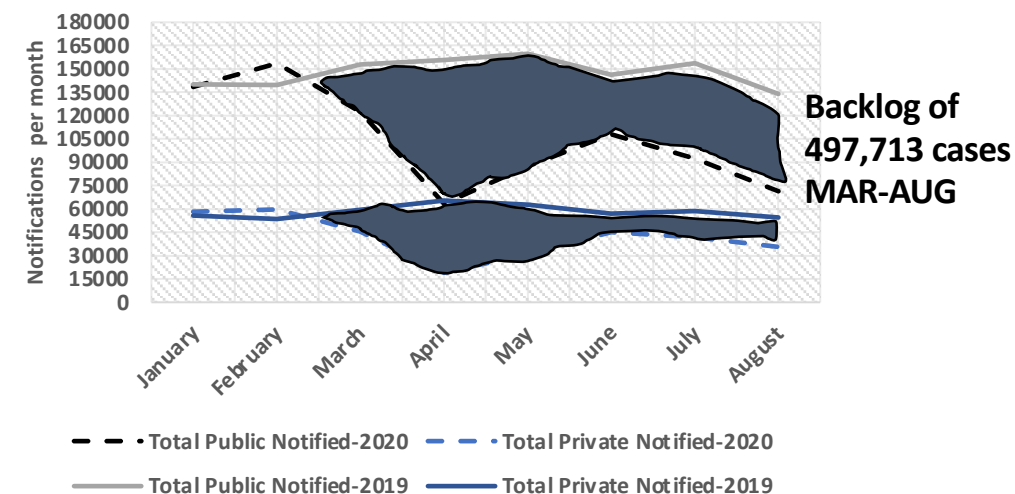
GLOBALLY

70%+ HEALTHCARE WORKERS

reported a decrease in the number of people coming to health facilities for TB testing.



Notifications India - 2020 vs 2019





COVID-19 HAS CHANGED THINGS...

COVID-19

WHO WE ARE

WHAT WE DO

NEWSROOM

PARTNERS & DONORS

CALLS FOR PARTNERS

COVID-19 A GLOBAL PERSPECTIVE

SARS-COV-2 DIAGNOSTIC PIPELINE

Home > Diagnostics & testing > SARS-CoV-2 diagnostic pipeline

FIND is collating an overview of SARS-CoV-2 tests that are commercially available or in development for the diagnosis of COVID-19. We do not guarantee that this is a comprehensive list, since the information below has been submitted voluntarily by test suppliers and is not independently verified. If you have any queries or wish for us to make updates in the pipeline, please [contact us](#).

If you would like your test to be included in the pipeline, please click on this button to download the form. [SUBMISSION FORM](#)

To know more about the ongoing test evaluations, please click on these buttons. [MOLECULAR ASSAY EVALUATIONS](#) [IMMUNOASSAY EVALUATIONS](#)

EUA: Emergency Use Authorization — HSA: Health & Safety/Sciences Authority — MFDS: Ministry of Food & Drug Safety — MoH: Ministry of Health — MHRA: Medicines & Health Care Products Regulatory Agency — NRA: National Regulatory Authority — RUO: Research Use Only — TGA: Therapeutic Goods Administration — WHO EUL: World Health Organization Emergency Use Listing

SHOW ALL	IMMUNOASSAYS	MOLECULAR ASSAYS	SAMPLE COLLECTION / INACTIVATION	DIGITAL SOLUTIONS	OTHER DIAGNOSTICS
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Status

Test format

Test target

Regulatory

FILTER

EXPORT TO XLS

799 RESULT(S)

- [1drop Inc.](#) [1copy™ COVID-19 qPCR Multi Kit](#) (Korea MFDS EUA - US FDA EUA - Health Canada - Saudi FDA - Sri Lanka NMRA - CE-IVD) [Contact](#)
- [3B BlackBio Biotech India Ltd](#) [TRUPCR® SARS-CoV-2 RT qPCR Kit](#) (India CDSCO - US FDA EUA) [Contact](#)
- [3D Medicines](#) [ANDiS® SARS-CoV-2 RT-qPCR Detection Kit](#) (US FDA EUA - CE-IVD) [Contact](#)
- [3D Medicines](#) [3DMed 2019-nCoV RT-qPCR Detection Kit](#) (CE-IVD) [Contact](#)
- [A*ccelerate Technology](#) [A*STAR Fortitude Kit 2.0](#) (Singapore HSA) [Contact](#)
- [AAZ-LMB](#) [COVID-PRESTO®](#) (CE-IVD) [Contact](#)

IN INDIA
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Notifications India - 2020 vs 2019

Notifications per month

Backlog of 497,713 cases MAR-AUG

Legend:
 - - • Total Public Notified-2020
 - - - • Total Private Notified-2020
 — Total Public Notified-2019
 — Total Private Notified-2019

Nikshay data, Sanjay Sarin FIND India

Number of patients at each step of cascade

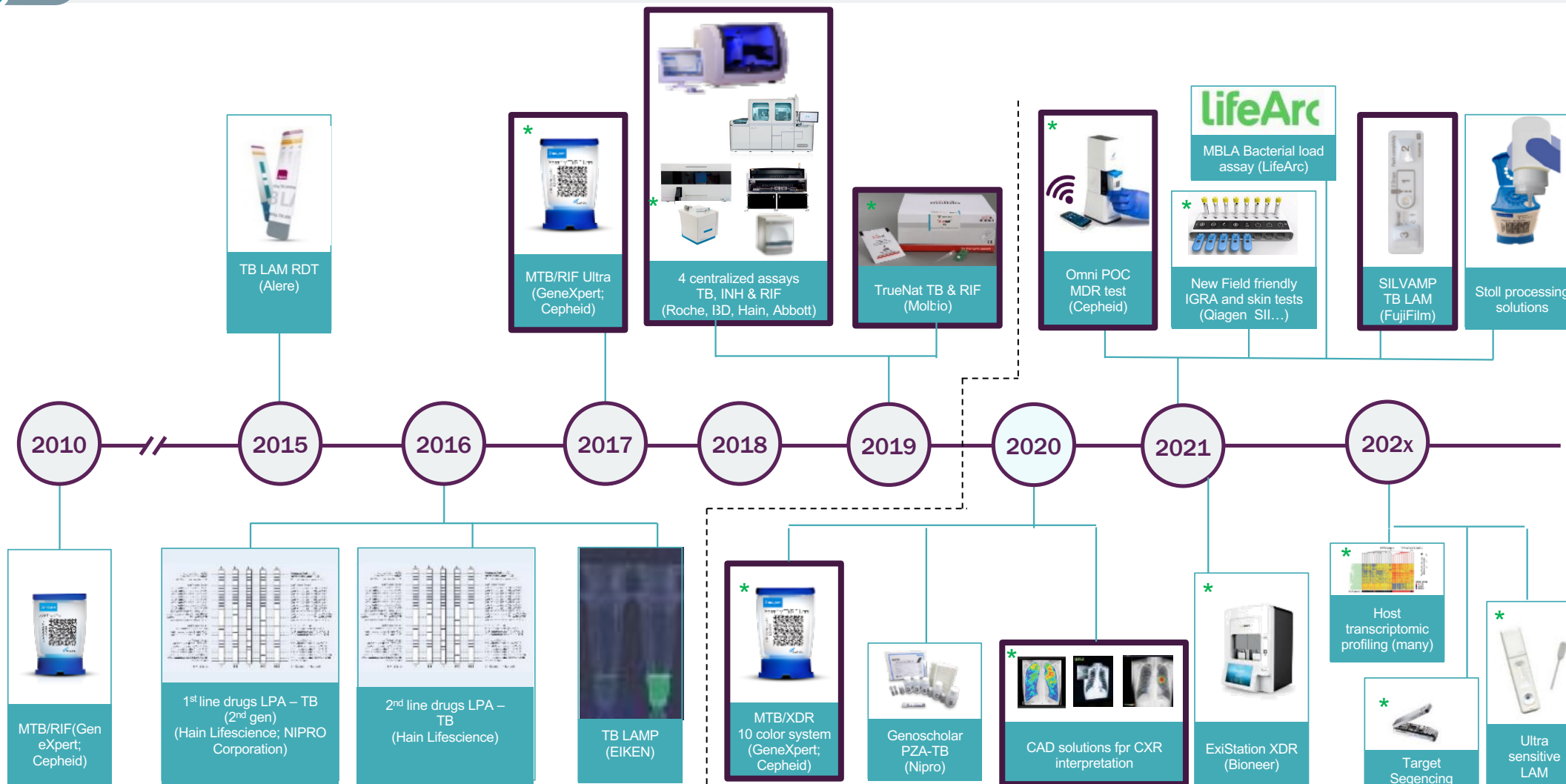
Step	Number of patients	Percentage
Individuals with incident TB	2,840,000	100%
Accessed TB tests	1,938,027	57%
Diagnosed with TB	1,629,906	50%
Registered in treatment	1,417,838	43%
Treatment success	1,221,764	37%
Recurrence-free survival	1,049,237	

<https://www.finddx.org/covid-19/pipeline>

3



A rich pipeline of connected TB diagnostics

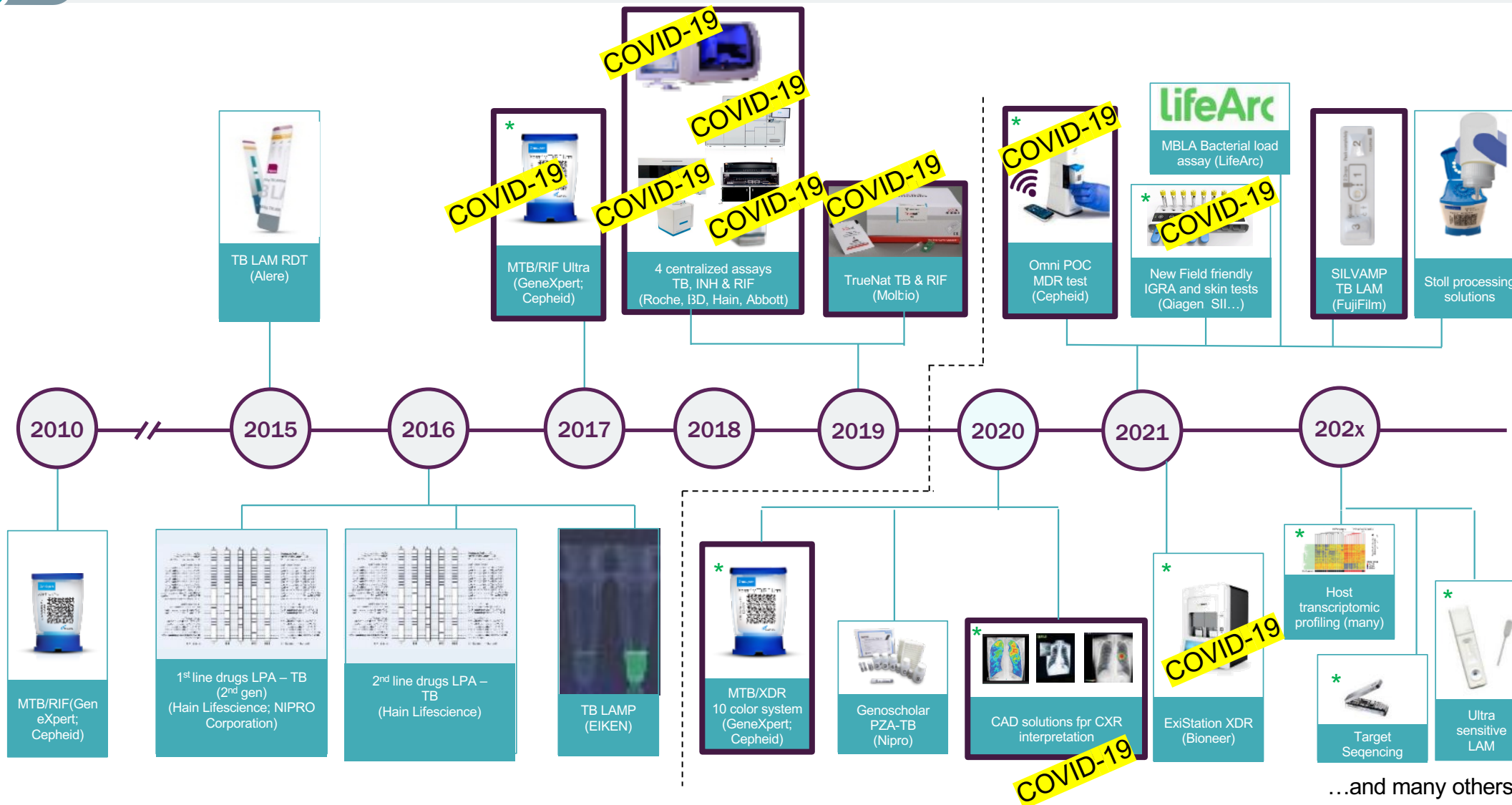


...and many others

* Connectivity enabled



A rich pipeline of connected TB diagnostics

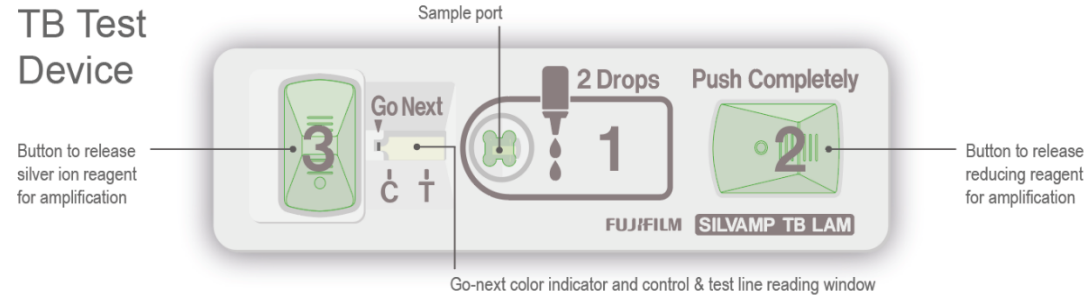


* Connectivity enabled



Fujifilm SILVAMP TB LAM

First in a new generation of highly sensitive LAM assays



Additional emerging data

- Children
- Extrapulmonary TB
- HIV-negative TB
- Mortality



Designed for the POC in LMIC's where patients seek care

Urine-based, rapid time-to-result, instrument-free and safe



Enhanced sensitivity to detect TB in all PLHIV

Around twice as sensitive compared to existing POC LAM assay



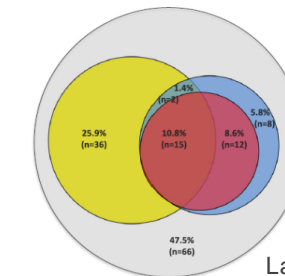
High Specificity for Immediate Treatment Initiation



High diagnostic yield

LAM based assays pick up patients faster and is complementary to sputum-based assays

Planned to support WHO review in 2021



Lawn *et al.* 2017



FujiLAM twice as sensitive as AlereLAM in PLHIV, first data on HIV negative

PLHIV (5 cohorts, n=1595)

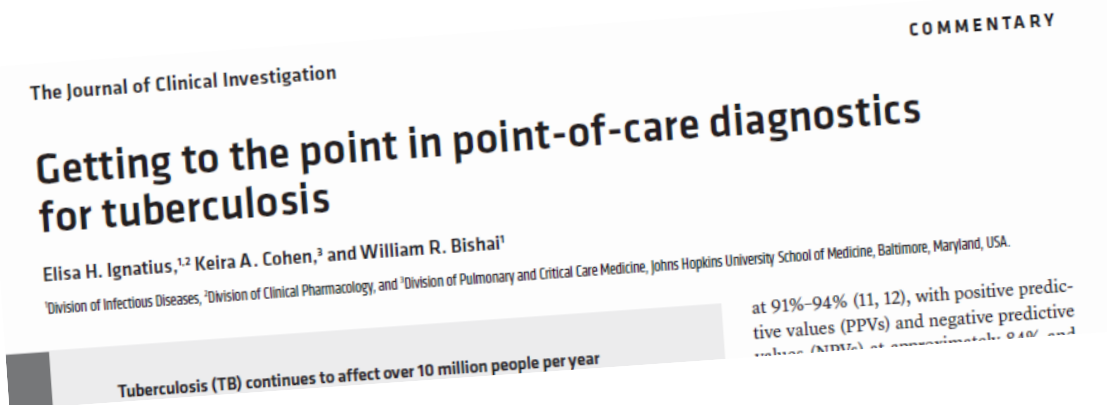
	N	Sn	[95% CI]	Sp	[95% CI]
FujiLAM	1595	70.7	[59.0 – 80.8]	90.9	[87.2 – 93.7]
AlereLAM	1595	34.9	[19.5 – 50.9]	95.3	[92.2 – 97.7]
Diff Sn and Diff Sp		35.8		-4.4	

Broger *et al*, PLOS Med 2020

HIV uninfected patients

Population	Site	Sensitivity % (95% C.I.)	Specificity % (95% C.I.)
Adults (n=187)	South Africa	25.0 (13.3 – 42.1)	98.1 (94.5 – 99.3)
Adults (n=185)	Peru	64.6 (53.6 – 74.2)	100.0 (96.5 – 100.0)

Broger et al. J Clin Invest 2020. (in press)





Digital xray with CAD

- offers new opportunities for TB and COVID-19 screening

Stop TB Partnership **AI4HLTH** **FIND**

Welcome to the **Stop TB Partnership** and **FIND** resource center on computer-aided detection products for the diagnosis of tuberculosis

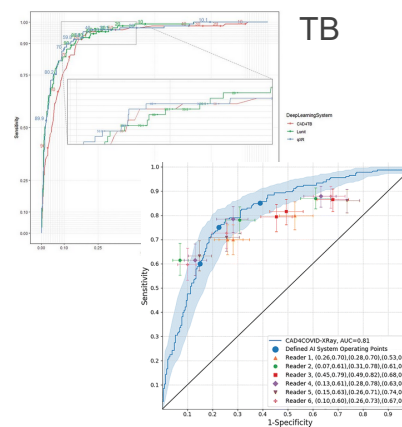
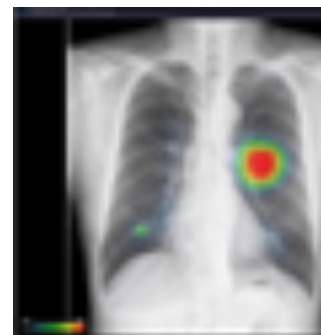
In recent years, the tuberculosis (TB) field has welcomed several computer-aided detection (CAD) products that provide an automated and standardized interpretation of digital chest X-rays based on artificial intelligence. The **AI4HLTH** resource center from the Stop TB Partnership and the Foundation for Innovative New Diagnostics (FIND) provides implementation-relevant information for a number of CAD products to assist country decision-making. Learn more about the features of available and upcoming CAD products for TB in the Products section below.

[Read more >](#)

AI Products for TB [Compare Products](#)

ARTELUS Telerad Certification: Pending (expected Q2 2021) Development Stage: Validation Intended Age Group: 18+ years	DEEPTIX DitiX Certification: CE-marked Development Stage: On the market Intended Age Group: 14+ years	DELFT IMAGING CAD4TB Certification: CE-marked Development Stage: On the market Intended Age Group: 4+ years	Dr CADx Dr CADx Certification: Pending (expected in 2021) Development Stage: Validation Intended Age Group: 16+ years
EPCON X-rayME Certification: Pending (expected Q1 2021) Development Stage: On the market Intended Age Group: 18+ years	infervision IntelliRAD Chest Certification: CE-marked Development Stage: On the market Intended Age Group: 18+ years (approved), 12-18 years	九和医疗 JH CAD-1 Certification: Pending (China NMPA 3 expected in mid-2020) Development Stage: On the market Intended Age Group: 15+ years	JLK JDOX (PNEUMONIA) Certification: CE-marked, Korea FDA, Australia FDA Development Stage: On the market Intended Age Group: 15+ years
Lunit INSIGHT CX Certification: CE-marked Development Stage: On the market Intended Age Group: 14+ years	quire.ai qR Certification: Pending Development Stage: On the market Intended Age Group: 0+ years (approved), 2+ years	RadiSen ARI Certification: Pending Development Stage: Validation Intended Age Group: 16+ years	

www.ai4hlth.org



Delft Light



FujiFilm CalneoXair



JLK inspection

Source: <https://www.delft.care/x-ray-systems/>; <http://jlkgroup.com/>;
<http://design.fujifilm.com/en/business/calneo-xair/>
 Murphy K, Radiology 2020; Qin et al Sci.rep. 2019; Yoo SH et al Frontiers 2020



Acknowledgments

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