

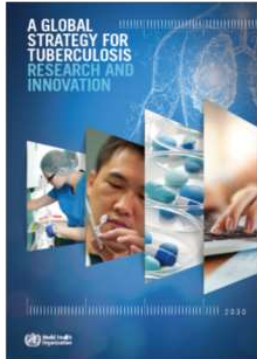
Developing new TB diagnostics: Needs, challenges and opportunities

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Stop TB Partnership, Geneva

30 October 2020

References



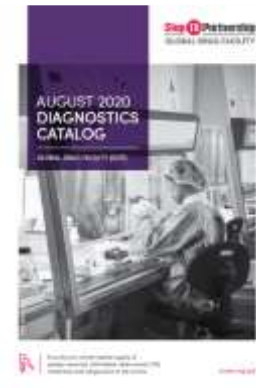
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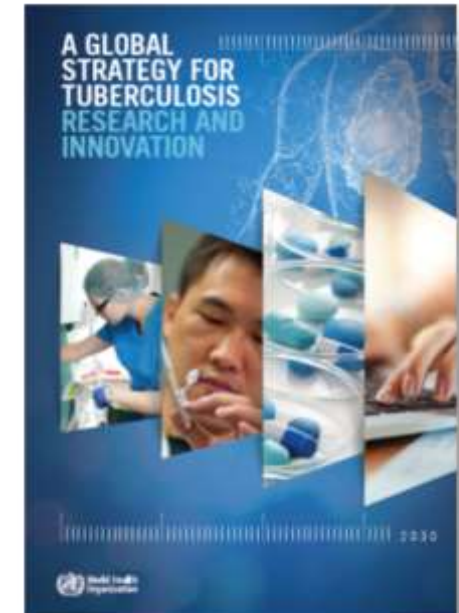
Global Plan to End TB 2018-2022 The Paradigm Shift. Stop TB Partnership; 2019
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GDF's Diagnostics Catalog. Stop TB Partnership; 2020
<http://www.stoptb.org/assets/documents/gdf/drugsupply/GDFDiagnosticsCatalog.pdf>

Highest priorities in TB diagnostics development include:

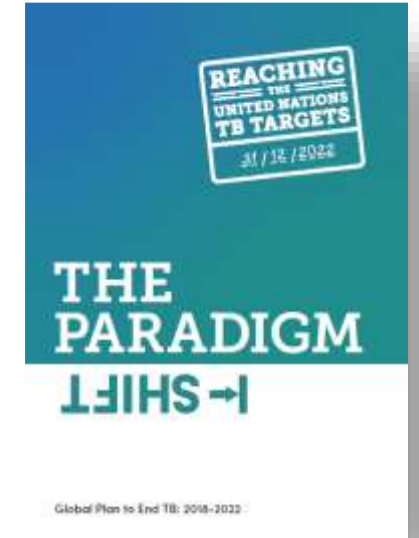
- **a biomarker test**: a point-of-care, non-invasive and non-sputum-based high accuracy test that can detect all forms of TB (TB infection, DS-TB and DR-TB) in all age groups and subpopulations by identifying characteristic biomarkers or biosignatures, and which can identify people more likely to develop TB disease after infection;
- **a triage test**: a point-of-care, simple, low-cost test that can be used by first-contact health care providers to identify those who need further testing;
- **a smear replacement test**: a more accurate (high sensitivity and specificity) point-of-care diagnostic test to replace smear microscopy for detecting pulmonary TB and to monitor treatment response for all subpopulations and age groups; and
- **a rapid drug susceptibility test**: a test that can be used at the microscopy centre level of the health care system to select appropriate first line regimen-based therapy



R&D priorities include

Stop TB Partnership

- Develop rapid and affordable non-sputum-based tests for diagnosis or triage.
- Develop accurate DST for critical medicines.
- Improve tools for detecting TB infection and testing for risk of progression to active disease.



FIND

- A user-friendly, low-cost, non-sputum-based rapid test for diagnosing active TB that can be used for active case-finding and in primary healthcare facilities.
- Rapid drug-resistance tests that enable treatment regimens to be tailored to individuals and help to safeguard medicines against AMR.



Progress in the development of TB diagnostics (1/4)

TECHNOLOGIES ENDORSED BY WHO

Molecular detection of TB and drug resistance

- Xpert MTB/RIF and Xpert Ultra as the initial diagnostic test for TB and rifampicin resistance, Cepheid, USA
- LPA for the detection of MTB, isoniazid and rifampicin resistance in acid-fast bacilli smear positive sputum or MTB cultures (FL-LPA), Hain Lifescience, Germany and Nipro, Japan
- LPA for the detection of resistance to fluoroquinolones and second-line injectable agents (SL-LPA), Hain Lifescience, Germany
- TB LAMP for detection of TB, Eiken, Japan
- Truenat MTB, MTB Plus and MTB-RIF Dx assays as initial diagnostic tests for TB and rifampicin resistance, Molbio Diagnostics, India

IGRAs for TB infection

- T-SPOT.TB, Oxford Immunotec, UK
- QuantiFERON-TB Gold Plus (QFT-Plus), Qiagen, USA

Culture-based technologies

- Commercial liquid culture systems and rapid speciation
- Culture-based phenotypic DST using 1% critical proportion in LJ,7H10,7H11 and MGIT media

Microscopy

- Light and light-emitting diode microscopy (diagnosis and treatment monitoring)

Biomarker based assays

- Alere Determine TB-LAM, Alere, USA for TB detection in HIV infected people

Progress in the development of TB diagnostics (2/4)

UNDER EVALUATION BY WHO

Molecular detection of TB and drug resistance

- Molecular technologies for genotypic drug resistance testing (including sequencing technologies)
- FluoroType MTBDR, Hain Lifescience, Germany
- m2000 RealTime MTB System, Abbott, USA
- BD Max MDR-TB, Becton Dickinson, USA
- Roche cobas[®] MTB system, Roche Diagnostics, Switzerland
- AccuPower TB & MDR RT PCR, Bioneer, Republic of Korea
- Genoscholar PZA TB II, Nipro, Japan
- Xpert XDR-TB cartridge, Cepheid, USA

CAD for digital chest radiography

- CAD4TB, Delft Imaging, Netherlands
- Lunit INSIGHT CXR, Lunit, South Korea
- qXR, qure.ai, India
- DxTB, Deeptek, USA
- XrayAME, Epcon, Belgium
- InterRead DR Chest, Inter VISION, China
- T-Xnet, Artelius, India
- Dr CADx, Dr CADx, Zimbabwe
- RediSen, AXIR, South Korea
- JF CXR-1, JF HEALTHCARE, China

Culture-based drug susceptibility testing

- Sensititre[™] MYCOTBI plate; ThermoFisher Scientific Inc., USA

Progress in the development of TB diagnostics (3/4)

ON THE MARKET (NOT YET EVALUATED BY WHO)

Molecular detection of TB and drug resistance

- iCubate System, iCubate, USA
- Genechip, TB drug resistance array, Capital Bio, China
- EasyNAT TB Diagnostic kit, Ustar Biotechnologies, China
- Amplification-based tNGS assays: Next Gen-RDST assay, TGen, USA;
- Deeplex-MycTB assay, GenoScreen, France

IGRAs for TB infection

- Lioferon TB/LTBI, LIONEX Diagnostics & Therapeutics GmbH, Germany
- STANDARD E TB-Feron ELISA, SD Biosensor, Republic of Korea
- Advansure TB IGRA, LG chem, Republic of Korea

Skin tests for TB infection

- Diaskintest, JSC Generium, Russian Federation

Progress in the development of TB diagnostics (4/4)

TECHNOLOGIES IN DEVELOPMENT

Molecular detection of TB and drug resistance

- Gendrive MTB/RIF ID, Epistem, UK
- TruArray MDR-TB, Akkoni, USA
- INFINITIMTB Assay, AutoGenomics, USA
- FluoroType XDR-TB assay, Hain Lifescience, Germany
- MeltPro TB assay, Zeesan Biotech, China
- QuantuMDx, POC, UK
- Truenat MTB-INH/MTB-FQ, Molbio, India
- AccuPower XDR-TB RT PCR, Bioneer, Republic of Korea

IGRAs for TB infection

- Access QuantiFERON®-TB, QIAGEN, USA
- IP-10 IGRA elisa/lateral flow, rBioPharm, Germany
- ichroma™ IGRA-TB, Boditech Med Inc., Republic of Korea
- T-Track(R) TB, Lophius Biosciences GmbH, Germany
- VIDAS TB-IGRA, bioMérieux, France

Skin tests for TB infection

- c-Tb skin test, Serum Institute of India, India
- EC-Test, Anhui Zhifei Longcom Biopharmaceutical Co. Ltd, China

PRICE - GDF's Diagnostics Catalog -



GENEXPERT GX-IV 4-MODULE SYSTEM WITH DESKTOP

Product Code: GXIV-4-D

GeneXpert 4-module instrument with desktop computer and barcode reader. This is the most commonly used configuration globally. Laptop version also available.

REAGENTS

CGXMTB-RIF-50	Xpert MTB/RIF kit of 50 tests	1 x 50 tests	499.00
GXMTB/RIF-ULTRA-50	Xpert MTB/RIF Ultra kit of 50 tests	1 x 50 tests	499.00



DETERMINE TB LAM AG TEST

Product Code: 106642

The Determine TB LAM Ag test is the first rapid, urine-based, point-of-care test for TB among people living with HIV. The product is supplied in kits of 100 tests (10 cards with 10 tests per card) with a reference scale card.

RAPID TESTING

106642	Determine TB LAM Ag	100	350.00
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Thanks

