

### List of TB Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy

According to Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and core Personal Protective Equipment (<https://www.theglobalfund.org/en/sourcing-management/quality-assurance/in-vitro-diagnostics/>), in force since 1st March 2011, Grant Funds may only be used to procure Diagnostic Products if they have been:

**Criterion 1-** prequalified by the WHO Prequalification of In Vitro Diagnostics Programme, or

**Criterion 2-** recommended by the WHO Global TB programme, or

**Criterion 3-** authorized for use by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed (Class C and D) or WLA within their scope of listing

**Criterion 4-** acceptable for procurement using Grant Funds, as determined by the Global Fund, based on the advice of the WHO Expert Review Panel

The list is an overview of Diagnostic Products to assist Principal Recipients (PRs) of Global Fund grants to identify the status of products according to the Global Fund Quality Assurance Policy. It includes products recommended for use after technical evaluation by WHO Prequalification of Diagnostics Programme, WHO Global TB programme recommendation, Regulatory Authorities of GHTF founding members, WLAs and the WHO hosted Expert Review Panel.

The list is not exhaustive; PRs can procure product(s) not listed below as long as PRs demonstrate that the product is compliant with one of the above mentioned requirements.

The list is updated regularly based on evidence received by the Global Fund.

### Lateral Flow Mycobacterial Lipoarabinomannan (LAM) tests for TB (TB-LAM)

\*  
 Product codes superscripted with a (star) mark indicates that product is WHO prequalified

Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Initial Sensitivity	Final Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
7D2741	Determine TB LAM Ag	25T/kit	see IFU	see IFU	Abbott Diagnostics Scarborough	lipoarabinomannan	urine	18 months / 2°C to 30°C		WHO Global TB program policy recommendation

N/A- NOT APPLICABLE

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**List of TB Diagnostic test kits and equipments eligible for procurement according to Global Fund QA Policy for Diagnostic Products**
**MTB Nucleic Acid Amplification Technologies**

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Manufacturer Product Catalogue number	Product Name (IVD reagent)	Number of tests per kit	Platform	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
08N15-090	Abbott RealTime MTB Amplification Reagent Kit	96T/kit	Abbott Realtime System	Abbott GmbH & Co KG, Wiesbaden, Germany	MTBC DNA	18 months	-25°C to -15°C	Sputum bronchial alveolar lavage		WHO Global TB program policy recommendation
08N28-090	Abbott RealTime MTB RIF/INH Resistance Amplification Reagent Kit	96T/kit	Abbott Realtime System	Abbott GmbH & Co KG, Wiesbaden, Germany	MTBC DNA	12 months	-25°C to -15°C	Sputum bronchial alveolar lavage		WHO Global TB program policy recommendation
443878	BD MAX™ MDR -TB	24T/kit	BD MAX™ System	Becton Dickenson & Co, BD Bioscience	MTBC DNA	9 months	2°C to 28°C	Sputum bronchial alveolar lavage		WHO Global TB program policy recommendation
GXMTB/RIF-10 GXMTB/RIF-50	Xpert MTB/RIF kit	10T/kit or 50T/kit	GeneXpert	Cepheid, Solna, Sweden	MTBC DNA	24 months	2°C to 28°C	- Sputum - bronchial alveolar lavage - selected extrapulmonary specimens	working with 6- and 10-color GeneXpert® modules;	WHO Global TB program policy recommendation
GXMTB/RIF-ULTRA-10 GXMTB/RIF-ULTRA-50	Xpert MTB/RIF kit Ultra	10T/kit or 50T/kit	GeneXpert	Cepheid, Solna, Sweden	MTBC DNA	24 months	2°C to 28°C	- Sputum - bronchial alveolar lavage - selected extrapulmonary specimens	working with 6- and 10-color GeneXpert® modules;	WHO Global TB program policy recommendation
GXMTB/XDR-10	Xpert MTB/XDR	10T/kit	GeneXpert	Cepheid, Solna, Sweden	MTBC DNA	8 months	see IFU	see IFU	requires 10-color GeneXpert® modules; For consumables and details of components refer to IFU	WHO Global TB program policy recommendation



## MTB Nucleic Acid Amplification Technologies

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Manufacturer Product Catalogue number	Product Name (IVD reagent)	Number of tests per kit	Platform	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
972000	Loopamp™ MTBC Detection Kit	96T/kit	HumaLoop	Eiken Chemical Co., Ltd, Tokyo, Japan (distributed by HUMAN Gesellschaft für Biochemica und Diagnostica mbH, Wiesbaden, Germany)	MTBC DNA	14 months	2°C to 30°C	Sputum bronchial alveolar lavage	For consumables and details of components refer to IFU	WHO Global TB program policy recommendation
62824 62896	FluoroType® MTBDR VER 2.0	24T/kit or 96T/kit	See IFU	Hain Lifescience GmbH, Germany	MTBC DNA	on request	-20°C to -18°C	see IFU		WHO Global TB program policy recommendation
601030005 601030020 601030050	Truenat™ MTB	5T/kit 20T/kit 50T/kit	Truelab™ Real Time Quantitative micro PCR Analyzers (Truelab UnoDx, Truelab DuoDx and Truelab QuattroDx micro-PCR machines)	Molbio Diagnostics Pvt. Ltd. Goa, India	MTBC DNA	24 months	2°C to 30°C	Sputum bronchial alveolar lavage	For consumables and details of components refer to IFU	WHO Global TB program policy recommendation
601130005 601130020 601130020	Truenat™ MTB Plus	5T/kit 20T/kit 50T/kit	Truelab™ Real Time Quantitative micro PCR Analyzers (Truelab UnoDx, Truelab DuoDx and Truelab QuattroDx micro-PCR machines)	Molbio Diagnostics Pvt. Ltd. Goa, India	MTBC DNA	24 months	2°C to 30°C	Sputum bronchial alveolar lavage	For consumables and details of components refer to IFU	WHO Global TB program policy recommendation
601210005 601210020 601210050	Truenat™ MTB Rif Dx	5T/kit 20T/kit 50T/kit	Truelab™ Real Time Quantitative micro PCR Analyzers (Truelab UnoDx, Truelab DuoDx and Truelab QuattroDx micro-PCR machines)	Molbio Diagnostics Pvt. Ltd. Goa, India	MTBC DNA	24 months	2°C to 30°C	Sputum bronchial alveolar lavage	For consumables and details of components refer to IFU	WHO Global TB program policy recommendation
8412197190	cobas® MTB	384T/kit	cobas®6800/8800 Systems	Roche Molecular Diagnostics, Pleasanton, USA	MTBC DNA	18 months	2°C to 8°C	Sputum bronchial alveolar lavage	being replaced by 9040579190	WHO Global TB program policy recommendation
9040579190	cobas® MTB	384T/kit	cobas®5800/6800/8800 Systems	Roche Molecular Diagnostics, Pleasanton, USA	MTBC DNA	24 months	2°C to 8°C	Sputum bronchial alveolar lavage		WHO Global TB program policy recommendation
7833326190	cobas® MTB-RIF/INH	72T/kit	cobas®6800/8800 Systems	Roche Molecular Diagnostics, Pleasanton, USA	MTBC DNA	24 months	2°C to 8°C	Sputum bronchial alveolar lavage	being replaced by 9040617190	WHO Global TB program policy recommendation

## MTB Nucleic Acid Amplification Technologies

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Manufacturer Product Catalogue number	Product Name (IVD reagent)	Number of tests per kit	Platform	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
9040617190	cobas® MTB-RIF/INH	192T/kit	cobas®5800/6800/8800 Systems	Roche Molecular Diagnostics, Pleasanton, USA	MTBC DNA	24 months	2°C to 8°C	Sputum bronchial alveolar lavage		WHO Global TB program policy recommendation

N/A- NOT APPLICABLE

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MTB Line Probe Assays

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Manufacturer Product Catalogue number	Product Name (IVD reagent)	Number of tests per kit	Platform	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
30496A	GenoType MTBDRplus Ver 2.0	96T/kit	see IFU	Hain Lifescience GmbH, Germany	MTBC DNA	on request	see IFU	see IFU		WHO Global TB program policy recommendation
317A 31796A	GenoType MTBDRsl Ver 2.0	12T/kit or 96T/kit	see IFU	Hain Lifescience GmbH, Germany	MTBC DNA	on request	see IFU	see IFU		WHO Global TB program policy recommendation

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IGRA testing for Latent TB Infection

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WT-1196	WANTAI TB-IGRA	28T/kit		Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	INF-y	see IFU	on request		WHO Global TB program policy recommendation
TB.300 + TSK.910	T-SPOT®.TB 8 with T-Cell Select	144T/kit		Oxford Immunotec Ltd	INF-y	see IFU	on request		GHTF (US FDA PMA)
TB.300 + TTK.610	T-SPOT®.TB 8 with T-Cell Xtend	40T/kit		Oxford Immunotec Ltd	INF-y	see IFU	on request		WHO Global TB program policy recommendation
	QuantiFERON®-TB Gold In-Tube	see IFU		Qiagen	INF-y	see IFU	on request	QIAGEN discontinued manufacturing of QFT-GIT and it is no longer available.	WHO Global TB program policy recommendation
622120 or 622130	QuantiFERON®-TB Gold Plus	2 x 96T/kit		Qiagen	INF-y	see IFU	on request		GHTF (US FDA PMA)
622822 or 622832		20 x 96T/kit							
10TBF10C	STANDARD™ E TB-Feron ELISA	see IFU		SD Biosensor Inc	INF-y	see IFU	on request	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERPD until 8th October 2024
on request	on request	on request		on request	INF-y	on request	on request	Further Products are available from ERPD as RISK CATEGORY-3 / Non-Objection-Letters are required for procurement	ERPD

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MTB Culture technologies

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Manufacturer Product Catalogue number	Product Name	Number of tests per kit	Sensitivity	Specificity	Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
245111	BD BBL MGIT Mycobacteria Growth Indicator Tubes 4ml with BD BACTEC MGIT 320 (441743) or 960 (445870)	25			BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	24 months / 2 to 25°C		WHO Global TB program policy recommendation
245113	BD BBL MGIT Mycobacteria Growth Indicator Tubes 4ml with BD BACTEC MGIT 320 (441743) or 960 (445870)	100			BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	24 months / 2 to 25°C		WHO Global TB program policy recommendation

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MTB species identification RDTs in liquid and solid culture

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CATBo870 CATBo871	Capilia TB-Neo	100T/kit 10T/kit	see IFU	see IFU	TAUNS Laboratories, Inc.	MPB64 antigens	culture specimen	on request		GHTF (EU IVDR)

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**List of TB Diagnostic test kits and equipments eligible for procurement according to Global Fund QA Policy for Diagnostic Products**
**targeted NGS for Drug resistant TB**

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Manufacturer Product Catalogue number	Product Name (IVD reagent)	Number of tests per kit	Platform	Manufacturer	Detection type	Anticipated Shelf life (months)	Recommended storage temperature	Specimen type	Comments	Eligibility WHO or GHTF countries
GNSDMTB01	Deplex Myc-TB	48T/kit	Illumina	Genoscreen	MTBC DNA	on request	see IFU	see IFU		WHO Global TB program policy recommendation
OND-TBDR001-XX	Oxford Nanopore Diagnostics (OND) Tuberculosis Drug Resistance Test	96T/kit	OND GridION Diagnostic Sequencing System	Oxford Nanopore Diagnostics	MTBC DNA	on request	see IFU	see IFU		WHO Global TB program policy recommendation

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