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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 Diagnostic Products (https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf), 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 (high risk classification),
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 programm recommendation, Regulatory Authoritities of GHTF founding members 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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MTB Nucleic Acid Amplification Technologies

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Manufacturer Product Catalogue number	Product Name (IVD reagent)	Reference detail	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, Sunnyvale, USA	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, Sunnyvale, USA	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, Sunnyvale, USA	MTBC DNA	8 months	see IFU	see IFU	requires 10-color GeneXpert® modules; For consumables and details of componants 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)	Reference detail	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 componants 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	Truenat™ MTB	5T/kit or 20T/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 componants refer to IFU	WHO Global TB program policy recommendation
601130005 / 601130020	Truenat™ MTB Plus	5T/kit or 20T/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 componants refer to IFU	WHO Global TB program policy recommendation
601210005 601210020	Truenat™ MTB Rif Dx	5T/kit or 20T/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 componants 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		WHO Global TB program policy recommendation
7833326190	cobas® MTB-RIF/INH	72T/kit	cobas®6800/8800 Systems	Roche Molecular Diagnostics, Pleasanton, USA	MTBC DNA	16 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)	Reference detail	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

N/A- NOT APPLICABLE

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IGRA testing for Latent TB Infection

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Manufacturer Product Catalogue number	Product Name	Number of tests per kit			Manufacturer	Analyte	Specimen Type	Anticipated Shelf life (months)/ Storage temperature	Comments	Eligibility WHO or GHTF countries
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	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	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								
622724	QIAreach™ QuantiFERON®-TB	50T/kit			Qiagen	INF-y	see IFU	on request	ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement	ERPD until 12th January 2024
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 2023
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

N/A- NOT APPLICABLE

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MTB species identification RDTs in liquid and solid culture

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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
on request	on request	on request	on request	on request	on request	on request	on request	on request	ERPD as RISK CATEGORY-3 products are available / Non-Objection-Letters are required for procurement	ERPD until 2nd May 2024

N/A- NOT APPLICABLE