THE GLOBAL FUND

Version 28
30 Sep 2026

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

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

N/A- NOT APPLICABLE

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

According to Global FundQuality 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 programm recommendation, Regulatory Authoritities 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)

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

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/RIF-ULTRA-HB-10 GXMTB/RIF-ULTRA-HB-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 PQ

MTB Nucleic Acid Amplification Technologies

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
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 componants refer to IFU	WHO PQ
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 PQ
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	For consumables and details of componants refer to IFU	WHO Global TB program policy recommendation
1880018	LiquidArray MTB-XDR VER 1.0	64T/kit	See IFU	Hain Lifescience GmbH, Germany	MTBC DNA	12 months	-20°C to -18°C	Sputum	For consumables and details of componants refer to IFU	GHTF (EU IVDR)
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 componants refer to IFU	WHO Global TB program policy recommendation
601130005 601130020 601130050	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 componants 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 componants refer to IFU	WHO Global TB program policy recommendation
09040579190	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 PQ

MTB Nucleic Acid Amplification Technologies

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
09040617190	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 PQ
11MTB30A	STANDARD™ M10 MTB RIF/INH	10T/kit	STANDARD M10 Console (Cat. No. 11M1011) and STANDARD M10 Module (Cat. No. 11M1012)	SD Biosensor, Inc., Republic of Korea	MTBC DNA	12 months	2°C to 28°C	Sputum sputum sediment		GHTF (EU IVDR)

N/A- NOT APPLICABLE

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MTB Nucleic Acid Amplification Technologies (NAAT) for Near Point of Care (NPOC)

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
RM1012202-10	MTB Nucleic Acid Test Card (IFU Version A/5 and higher)	10T/kit	Integrated Nucleic Acid Testing Device Pluslife MiniDock (PM001 Ultra)	Guangzhou Pluslife Biotech Co., Ltd., China	MTBC DNA	13 months	0°C to 40°C	Sputum or Tongue swab	For consumables and details of componants refer to IFU Version A/5 and higher)	ERPD until 29th January 2027

N/A- NOT APPLICABLE

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

IGRA testing for TB Infection

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
SMFP-99	AFIAS IGRA-TB	24/kit			Boditech Med Inc	INF-y	see IFU	on request		GHTF (EU IVDR)
CFPC-86	ichroma™ IGRA-TB	150/kit			Boditech Med Inc	INF-y	see IFU	on request		GHTF (EU IVDR)
CFPC-86-1	ichroma™ IGRA-TB-25	150/kit			Boditech Med Inc	INF-y	see IFU	on request		GHTF (EU IVDR)
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								
TC8806	RIDAScreen TB	56T/kit			R-Biopharm AG	INF-y	see IFU	on request		GHTF (EU IVDR)
TN8802	RIDAQuick TB	25T/kit			R-Biopharm AG	INF-y	see IFU	on request		GHTF (EU IVDR)
07TBF10C	STANDARD™ E TB-Feron ELISA	see IFU			SD Biosensor Inc	INF-y	see IFU	on request		WHO Global TB program policy recommendation
10TBF30E	STANDARD™ F TB-Feron FIA (IFN-gamma)	see IFU			SD Biosensor Inc	INF-y	see IFU	on request		GHTF (EU IVDR)

IGRA testing for TB Infection

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
N/A- NOT APPLICABLE										

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MTB Line Probe Assays

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

MTB Liquid culture technologies for diagnosis with/without Drug Susceptibility Testing (DST)

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	12 months / 2 to 25°C	For DST the following drug substances are available: Kanamycin Moxifloxacin Amikacin Capreomycin Ofloxacin Ethionamide p-aminosalicylic acid Bedaquiline	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	12 months / 2 to 25°C		WHO Global TB program policy recommendation
245122	BD BBL MGIT Mycobacteria Growth Indicator Tubes 7ml with BD BACTEC MGIT 320 (441743) or 960 (445870)	100			BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	12 months / 2 to 25°C		WHO Global TB program policy recommendation
245128	BD BACTEC MGIT 960 PZA Kit				BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	13 months / 2 to 25°C	For consumables see IFU	GHTF (EU-IVDR)
245123	BD BACTEC MGIT 960 SIRE Kit				BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	18 months / 2 to 25°C	For consumables see IFU	GHTF (EU-IVDR)
245125	BD BACTEC MGIT 960 STR 4.0 Kit				BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	18 months / 2 to 25°C	For consumables see IFU	GHTF (EU-IVDR)
245126	BD BACTEC MGIT 960 INH 4.0 Kit				BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	18 months / 2 to 25°C	For consumables see IFU	GHTF (EU-IVDR)
245157	BD BACTEC MGIT 960 IR Kit				BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	18 months / 2 to 25°C	For consumables see IFU	GHTF (EU-IVDR)
245127	BD BACTEC MGIT 960 EMB 7.5 Kit				BD Life Sciences - Integrated Diagnostic Solutions		all but blood and urine	18 months / 2 to 25°C	For consumables see IFU	GHTF (EU-IVDR)

N/A- NOT APPLICABLE

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MTB species identification RDTs in liquid and solid culture

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
245159	BD MGIT TBc Identification (TBc ID) Test	25T/kit	see IFU	see IFU	Becton Dickinson and Company	MPT64 antigens	culture specimen	on request		GHTF (EU IVDR)
CATB0870 CATB0871	Capilia TB-Neo	100T/kit 10T/kit	see IFU	see IFU	TAUNS Laboratories, Inc.	MPB64 antigens	culture specimen	on request		GHTF (EU IVDR)

N/A- NOT APPLICABLE

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