

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 programme recommendation, Regulatory Authorities 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)

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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

Disclaimer: The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.

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 (excluding Line Probe Assays)

Product codes superscripted with a * (star) mark is WHO prequalified

| 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 GHF 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 Dickinson & Co, BD Bioscience | MTBC DNA | 9 months | 2°C to 28°C | Sputum bronchial alveolar lavage | | WHO Global TB program policy recommendation |
| CGXMTBRIF | Xpert MTB/RIF kit | 10T/kit or 50T/kit | GeneXpert | Cepheid, Sunnyvale, USA | MTBC DNA | 9 months | 2°C to 28°C | - Sputum - bronchial alveolar lavage - selected extrapulmonary specimens | For consumables and details of components refer to IFU | 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 | 9 months | 2°C to 28°C | - Sputum - bronchial alveolar lavage - selected extrapulmonary specimens | For consumables and details of components refer to IFU | WHO Global TB program policy recommendation |
| GXMTB/XDR-10 | Xpert MTB/XDR | 10T/kit | GeneXpert | Cepheid, Sunnyvale, USA | MTBC DNA | see IFU | 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 (excluding 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 |
|---------------------------------------|-----------------------------|--------------------|---|--|----------------|---------------------------------|---------------------------------|-------------------------------------|--|---|
| 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 | GenoXtract 96 (catalog no. 900044)/FluoroCycler®XT (catalog no. 2017) | 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 components 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 components 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 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 | | 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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List of TB Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy
IGRA testing for Latent TB Infection

*** (star) mark indicates that product is WHO prequalified**

| 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 | see IFU | ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement | ERPD until 8th October 2021 |
| TB.300 + TSK.910 | T-SPOT®.TB 8 with T-Cell Select | 144T/kit | | Oxford Immunotec Ltd | INF-y | see IFU | see IFU | ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement | ERPD until 8th October 2021 |
| TB.300 + TTK.610 | T-SPOT®.TB 8 with T-Cell Xtend | 40T/kit | | Oxford Immunotec Ltd | INF-y | see IFU | see IFU | | WHO Global TB program policy recommendation |
| | QuantiFERON®-TB Gold In-Tube | see IFU | | Qiagen | INF-y | see IFU | see IFU | 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 | see IFU | | 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 | see IFU | ERPD as RISK CATEGORY-2 / Non-Objection-Letters are required for procurement | ERPD until 8th October 2021 |

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List of TB Diagnostic test kits and equipments classified according to the Global Fund Quality Assurance Policy
MTB species identification RDTs in liquid and solid culture

*** (star) mark indicates that product is WHO prequalified**

| 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 |
|---------------------------------------|----------------------------------|-------------------------|-------------|-------------|--------------------------|-------------|--------------------------|--|----------|---|
| 08FK50 | SD Bioline TB Ag MPT64 Rapid | | 98.6% | 100% | Abbott Rapid Diagnostics | TB Ag MPT64 | liquid and solid culture | 1°C to 30°C | | WHO Global TB program policy recommendation |
| 245159 | BD MGIT™ TBc Identification Test | 25T/kit | 100.0% | 100% | Becton Dickinson | TB Ag MPT64 | liquid and solid culture | see IFU | | WHO Global TB program policy recommendation |
| CATBo870 CATBo871 | Capilia TB-Neo | 100T/kit 10T/kit | 100.0% | 100% | TAUNS Laboratories, Inc. | TB Ag MPB64 | liquid and solid culture | 2°C to 30°C | | WHO Global TB program policy recommendation |

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**List of MTB products deleted/delisted
 Products not eligible for procurement**

All Technologies

| Manufacturer Product Catalogue number | Product Name | Number of tests per kit | Manufacturer | Deleted period | Reason for deletion/delisting |
|--|---------------------------|------------------------------------|--------------------------|---------------------------|--------------------------------------|
| 7D2740 | Alere Determine TB LAM Ag | 100T/kit | Abbott Rapid Diagnostics | Oct-20 | replaced by 7D2741 |