Stop TB Partnership
GLOBAL DRUG FACILITY

Stop TB Partnership's Global Drug Facility: Availability of TB diagnostics, Medical Devices and Health Products

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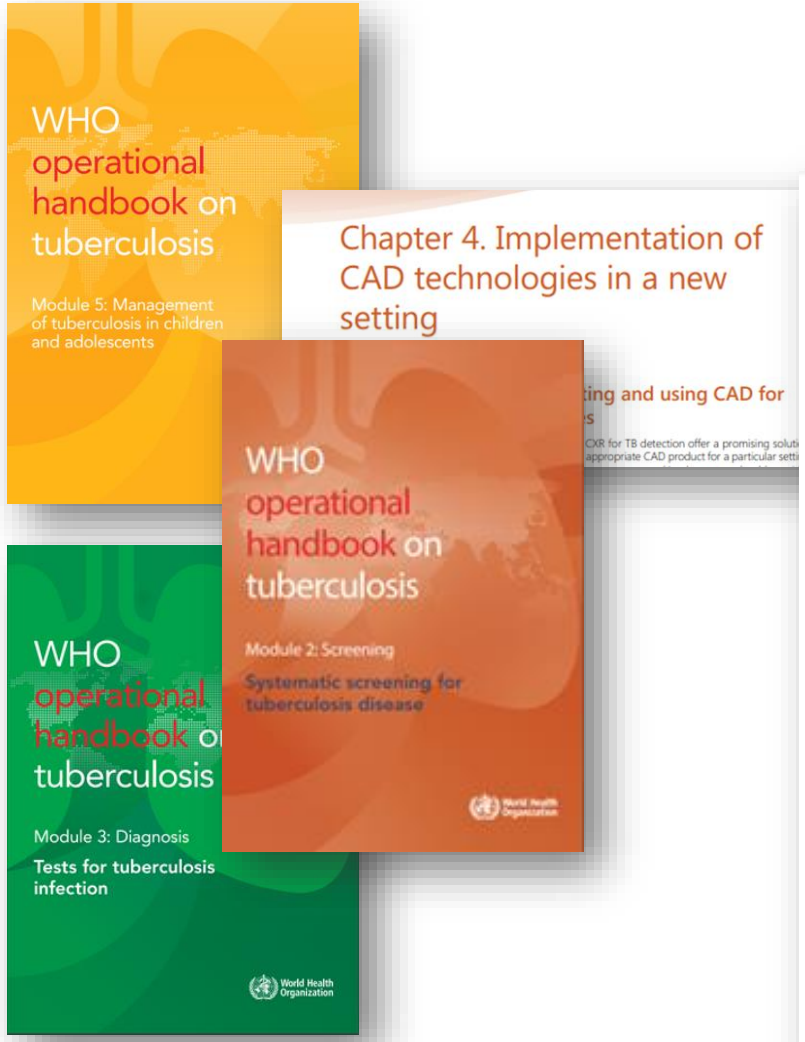
Presentation outline

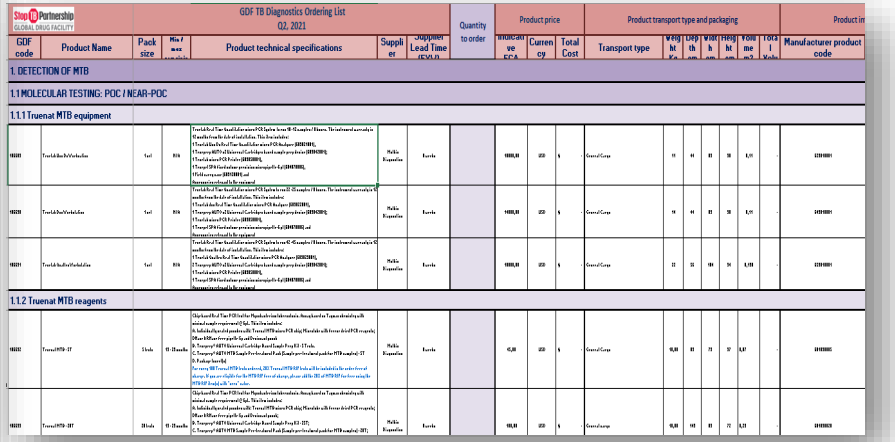
- TB diagnostics, Medical Devices and other Health Products
  - GDF catalogue
  - GDF timeline
  - Procurement using State Funds in EECA countries
  - Detailed information on Products
  - Additional resources for procurement via GDF
- Take home Points

TB diagnostics, Medical Devices and other Health Products Catalog, Global Drug Facility

https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog



More than 500 diagnostics products, diagnostic devices and reagents, together with the consumables for all levels of laboratories are available in the GDF catalogue at the best prices and access terms



GDF timeline: TB diagnostics, Medical Devices and other health products

2007
- Microscopy kits and supplies (30 items)

2010
- BD Liquid culture (39 items)
- General laboratory supplies (407 items)

2011
- GeneXpert 6 color (28 items)

2012
- Abbott Rapid speciation test* (1 item)
- HAIN Line Probe Assays (13 items)
- ZEISS LED microscopy supplies (4 items)

2016
- TAUNS Rapid speciation test (2 items)

2017
- Human Diagnostics Worldwide TB LAMP (11 items)
- MEG Bright field microscopy supplies (3 items)

2018
- Abbott Determine TB LAM Ag (1 item)

2019
- Cepheid GeneXpert Edge (14 items)
- QIAGEN IGRA (6 items)

2020
- Oxford Immunotec IGRA (6 items)
- BD COVID-19 tests (2 items)
- Cepheid COVID-19 tests (1 item)
- NIPRO Line Probe Assays (2 items)

2021
- molbio Truenat (21 items)
- General lab supplies (450 items)
- AMEX General lab supplies (60 items)
- avantor General lab supplies (6 items)
- NIPRO Genoscholar-PZA TB II (1 item)
- Cepheid GeneXpert 10 color (24 items); Xpress SARS-CoV-2 & MTB/RIF Ultra tests bundles (8 items)
- DELFT IMAGING X-ray system + CAD software (10 items)
- FUJIFILM X –Ray system (4 items)
- InferVision CAD software (5 items)
- SAVICS Connectivity solution (22 items)

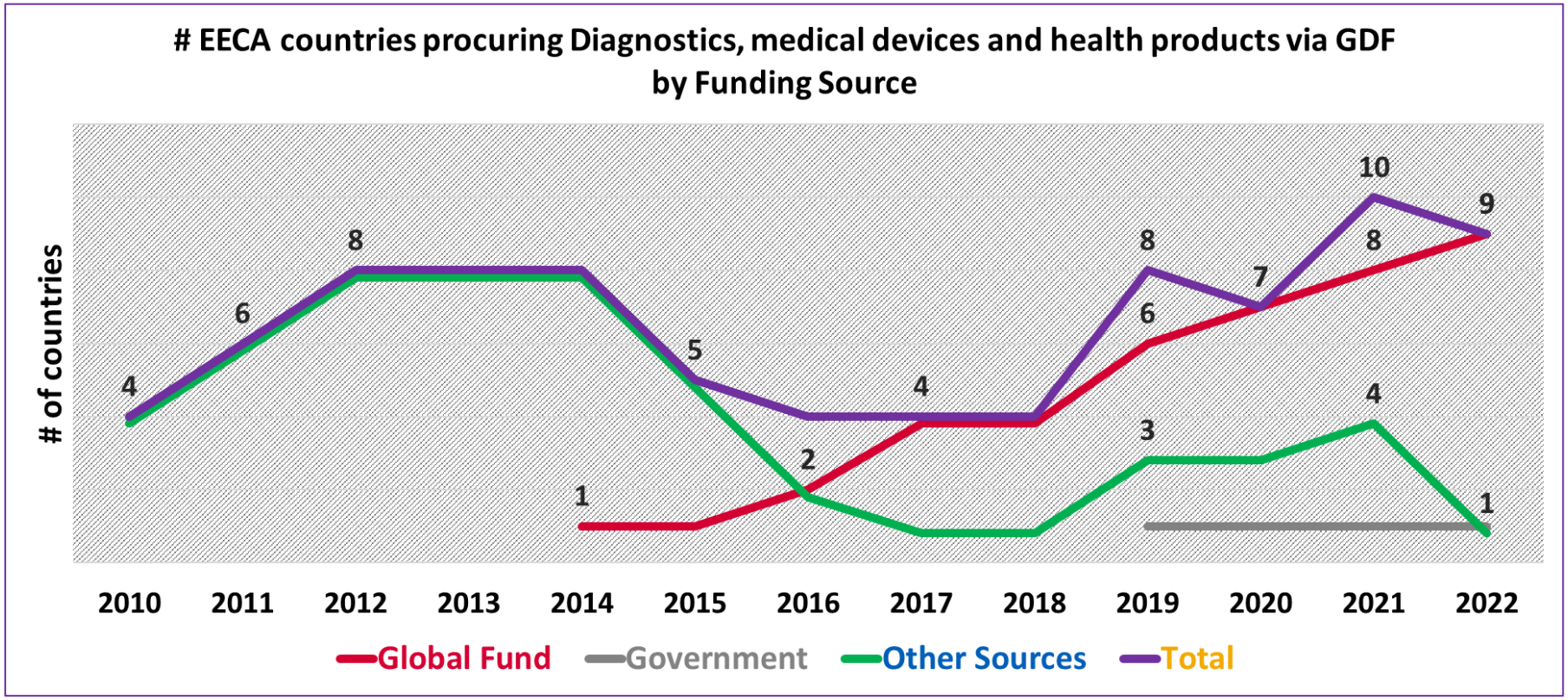
2022
- BD BD MAX (16 items)
- QIAGEN QiaReach* (2 items)

*TEMPORARILY SUSPENSION OF DIAGNOSTICS PRODUCTS IN THE GDF CATALOG

Procurement of TB diagnostics, Medical Devices and other Health Products using State Funds in EECA countries

There are no "GDF Countries" - All EECA countries are eligible to procure through GDF, in line with national regulations

Political Declaration on the Fight against TB – UNHLM (Sept 2018), decision point #15, encourages all nations to use the Stop TB Partnership/Global Drug Facility



WHO-recommended rapid diagnostic tests

- Molecular WRDs -
  - Xpert MTB/RIF, Xpert MTB/RIF Ultra
  - Truenat MTB, Truenat MTB Plus
- Moderate complexity automated NAATs -
  - BD MAX MDR-TB (Becton Dickinson)
- Low complexity automated NAATs - Xpert MTB/XDR Assay
- LPAs
  - LPAs; GenoType® MTBDRplus and GenoType® MTBDRsl, HAIN Lifescience;
  - NTM+MDRTB Detection Kit, NIPRO Corporation
- High complexity reverse hybridizationbased NAATs – Genoscholar PZA-TB II (Nipro)

One-slot fully automatic real time microPCR analyzer

BD MAX™ System

BD MAX is a fully integrated and automated real-time PCR centralized platform which can run up to 24 tests at a time.

FluoroType MTBDR and FluoroType MTB (Bruker/Hain Lifescience) – GDF is working to add to the catalog

Informational notes from Cepheid

June 2022

Discontinuation of 6-color GeneXpert System sale; technical support and modules replacement are available.

10-color technology allows to use Xpert MTB/RIF Ultra and MTB/XDR tests

Drug resistance	Gene Target
Isoniazid	inhA promoter (for Eto also)
	katG
	fabG1
	oxyR-ahpC intergenic region
Fluoroguinolones	gyrA
	gyrB
Amikacin	rrs
	eis promoter

July 2022

Discontinuation of the Xpert MTB/RIF and transition to the Xpert MTB/RIF Ultra tests

Characteristic	Xpert MTB/RIF	Xpert MTB/RIF Ultra
Turn around time	110 min	**<80 min**
Limit of detection	131 cfu/ml	**11.8 cfu/ml**
Targets	rpoB gene (5 probes)	rpoB gene (4 probes); **Detection of 2 different multi-copy (2 probes)**
Semi-Quantification	High, medium, low, very low	High, medium, low, very low, **tracy**

2022.06.22_cepheid_customer_information_genexpert-10-color_system_final_web.pdf (stoptb.org)
2022.07.12_cepheid_customer_informatio_genexpert_mtb_rif_2022_final_web.pdf (stoptb.org)

GeneXpert Systems'upgrade with 10-color Technology

Option 1

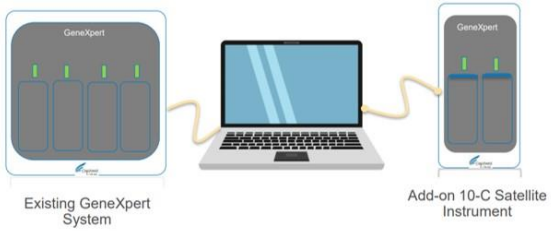
To order a new GeneXpert system with 10 color technology

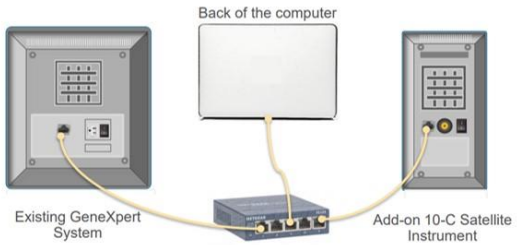
- Win10 computer
- Barcode scanner
- Latest GeneXpert software
- All accessories

GeneXpert IV, 10-color with Laptop
2 modules – 13.280 USD
4-modules – 19.500 USD

Option 2

Daisy chain a new GeneXpert instrument to an existing GeneXpert system.
The Daisy Kit allows connection of 2 to 4 instruments to the same computer.





GeneXpert IV, 10-color, Satellite*
2-modules – 9.780 USD
4 modules – 16.200 USD
Daisykit - 75 USD

* requirements
Win7 or 10 computer; Uninterruptible Power Supply; GeneXpert DX software 6.2 is required per site for Xpert MTB/XDR testing

Phenotypic and genotypic drug susceptibility tests

- New treatment regimens and new definitions on pre-XDR and XDR-TB have important implications for scaling up the detection of resistance to Fq, Bdq, Lzd
- Pure substances for **all** first- and second-line TB medicines recommended for DST are **available in GDF Catalog, EXCEPT:**
  - **Bedaquiline: Free through the NIH AIDS Reagent Program:** *https://www.hivreagentprogram.org*
  - **Delamanid: Free through the ATCC BEI Program:** *https://www.beiresources.org/About/BEIResources.aspx*
- **Pretomanid: DST protocol and critical concentrations not yet established by WHO**

http://stoptb.org/assets/documents/resources/publications/sd/BDQ_DEL_access.pdf

Medical devices

ULTRAPORTABLE DIGITAL X-RAY SYSTEMS

- FDR Xair
  - FDR Xair System Full kit
  - FDR Xair System Full kit Installation and Training
  - FDR Xair System Full kit Warranty Extensions (1 year and 3 years)
- Delft Light
  - Delft Light Full kit
  - Delft Light Full kit Installation and Training
  - Delft Light Full kit Warranty Extensions (1 year and 3 years)

CAD-AI SOFTWARE

Computer-Aided Detection based on Artificial Intelligence (CAD-AI) software for interpretation of digital chest X-ray (CXR) in screening and triage of adults and adolescents for TB disease

- InferRead DR Chest Software
  - InferRead DR Chest Software
  - InferRead DR Chest Laptop Server
  - InferRead DR Chest Installation and Training
  - InferRead DR Chest Support and Maintenance Extensions (1 year and 3 years)
- CAD4TB Software
  - CAD4TB Software (Perpetual License)
  - CAD4TB box
  - CAD4TB Installation and Training
  - CAD4TB Support and Maintenance Extensions (1 year and 3 years)

Ultraportable digital X-ray systems

More than 20 portative X-ray were procured by 6 countries in the EECA region

Characteristics/Medical Device	FDR Xair	Delft Light
Easy to transport	Lightweight	packed in a backpack
Power	light build-in lithium polymer batteries	battery-powered and runs on solar energy
Daily workload	100+ images on a single charge	200 exposures per-day
Cost	~ USD 47,000	~ USD 67,000
Installation, training and warranty extension for 1 year	~ USD 5,000	~ USD 5,000
Note	excluding pediatric and neonatal exams	children from age 4+

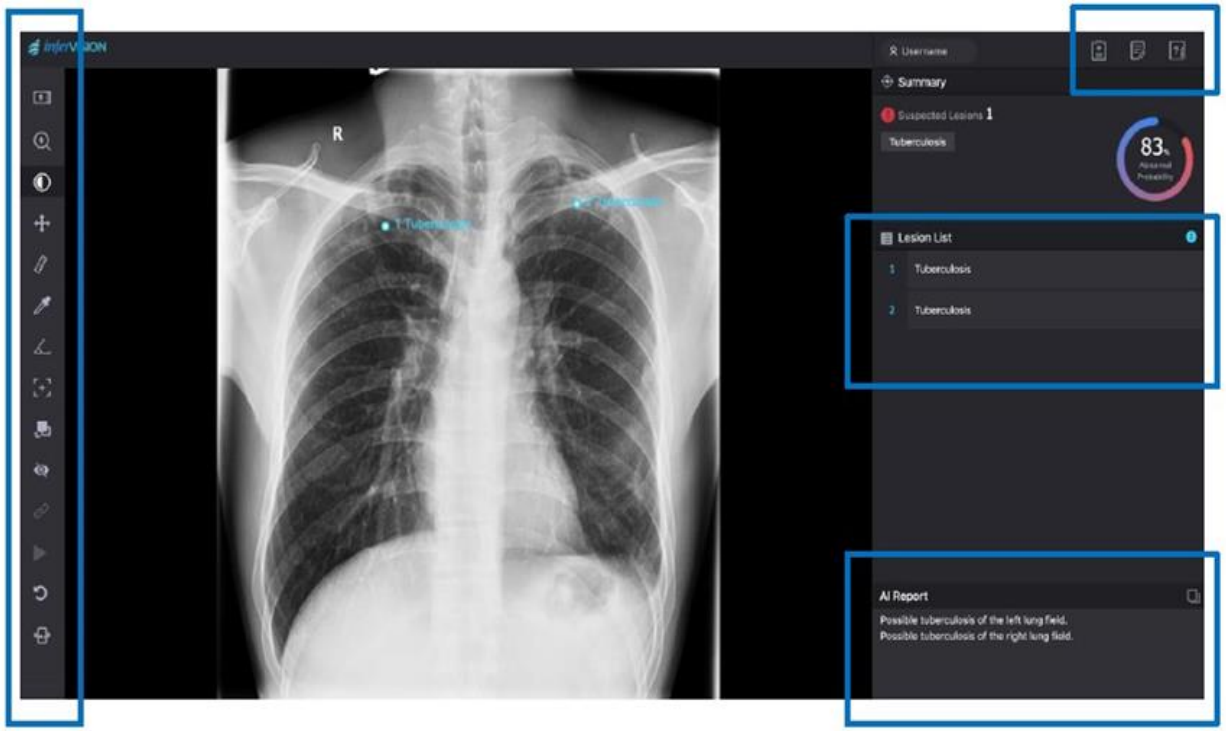
Computer-Aided Detection based on Artificial Intelligence software

More than 20 portative CAD-AI software procured by 5 countries in the EECA region

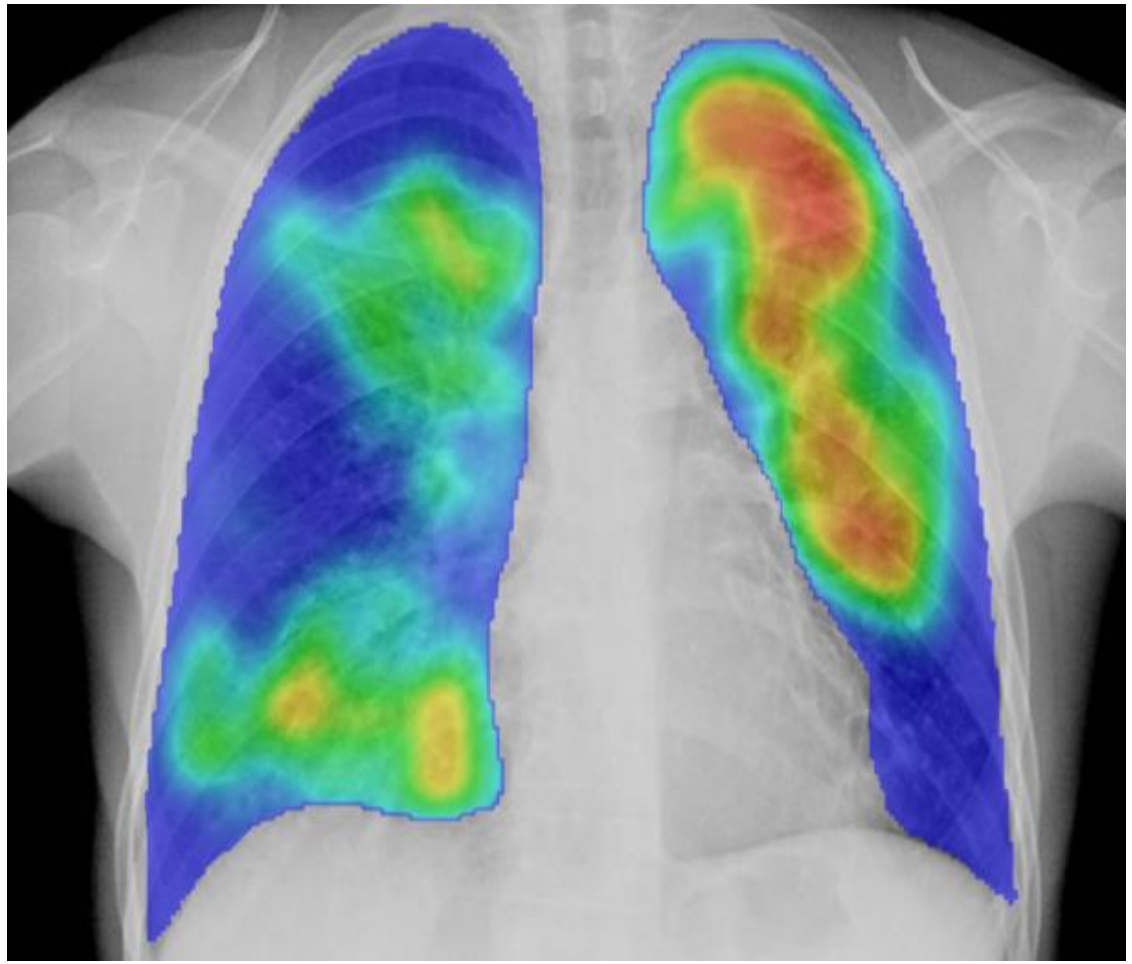
Characteristics/Software	InferRead DR Chest Software	CAD4TB Software
Outputs	Abnormality score for TB Heat Map	Abnormality score for TB Heat Map
Deployment	Online, offline, hybrid	Available for online (CAD4TBCloud) and offline (CAD4TBBox)
Age	from 16 years and above	adults and children from age 4+
Cost	InferRead DR Chest Software Perpetual License - $2,700 InferRead DR Chest laptop for offline use- $2,082	CAD4TB Software Perpetual License - $12,750 CAD4TB offline box - $2,750

Visualization of the CAD-AI

InferRead DR Chest Software



CAD4TB Software



WHO-recommended tests for TB infection

Box 1.2. Summary of WHO recommendations on TB infection tests *(14)*

Mycobacterium tuberculosis antigen-based skin tests (TBSTs) may be used to test for TB infection.
(Conditional recommendation for the intervention, very low certainty of the evidence)

Either a tuberculin skin test (TST) or interferon-gamma release assay (IGRA) can be used to test for LTBI.
(Strong recommendation, very low certainty of the evidence)

IGRAs (and the TST) should not be used in low- and middle-income countries for the diagnosis of pulmonary or extrapulmonary TB, nor for the diagnostic work-up of adults (including HIV-positive individuals) suspected of active TB in these settings.
(Strong recommendation)

HIV: human immunodeficiency virus; IGRA: interferon-gamma release assay; LTBI: latent tuberculosis infection; TB: tuberculosis; TBST: *Mycobacterium tuberculosis* antigen-based skin test; TST: tuberculin skin test; WHO: World Health Organization.

- **TB infection skin test using tuberculin (TST)**
- **TB infection skin tests using M. tuberculosis-specific antigens**
  - Cy-Tb (C-Tb test, Serum Institute of India)
  - Diaskintest (Generium, Russian Federation)
  - C-TST (ESAT6-CFP10 test, Anhui Zhifei Longcom, China)
- **Interferon-gamma release assays (blood tests for TB Infection)**
  - ELISA-based QFT-Plus
    - QuantiFERON®-TB Gold Plus (QFT-Plus)
    - ELISA-based WANTAI TB-IGRA (Beijing Wantai Biological Pharmacy Enterprise Co Ltd, Beijing, China)
  - ELISPOT-based T-SPOT.TB

Challenges related to tests for TB infection

Tuberculin Skin Tests
- Cold-chain requirements
- Supply constraints of QA products, even for HICs
- Low demand (GDF gets inquiries 1-2x/year)

IGRAs
- High cost
- Laboratory requirements/infrastructure
- Specimen referral
- Ancillary supplies
- Some have a low shelf life

IGRA in GDF catalog

GDF Diagnostics, Medical Devices and other health product catalogue
https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog

Qiagen QFT-Plus

- ~$15.90 per test (excluding generic consumables)
  - 60% reduction compared to high-income market price
- Concessional price available to most LMICs and some HICs
- Requires proprietary ELISA kit and blood collection tubes

Oxford Immunotec T-SPOT

- ~$10-13.50 per test (excluding generic consumables
- Supplier restrictions exclude GDF sales to some LMICs, HICs and US-embargoed countries

Additional resources - Technical Information Notes

https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog

Table 2. Number of Ultra cartridges that would be used in 1 year (260 working days1)

AVERAGE NUMBER OF TESTS PER MODULE PER DAY	GENEXPERT MODEL		
	2-MODULE GENEXPERT	4-MODULE GENEXPERT	16-MODULE GENEXPERT
5 (100% utilization)	2,600	5,200	20,800
4 (80% utilization)	2,080	4,160	16,640
3 (60% utilization)	1,560	3,120	12,480
2 (40% utilization)	1,040	2,080	8,320
1 (20% utilization)	520	1,040	4,160

[1] Number of working days should be adjusted according to country

FORECASTING AND ORDER PLANNING FOR ROLLING OUT LAMP

ESTIMATING EXPECTED TESTING VOLUMES

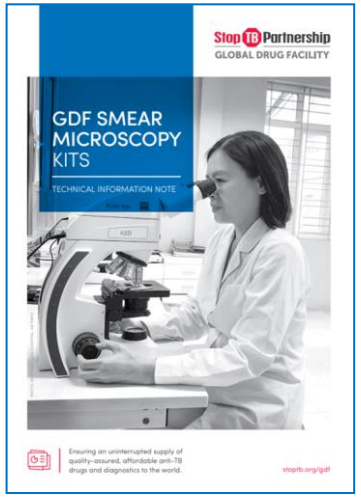
- Used as a replacement for smear microscopy to diagnose TB, the average daily number of people with signs or symptoms of TB at planned implementation sites should be used to estimate the expected testing volumes.

DEVICE THROUGHOUT

- Up to 14 patient samples can be run per cycle using the HumaLoop T equipment.
  - → Each cycle also requires a negative and positive control, so maximizing a batch size results in improved cost efficiency.
- Given each cycle takes 1.5 hours, 5 cycles may be run per day in a well-functioning laboratory (up to 70 patient samples per day). In laboratories starting to use the test, 2-3 cycles per day (28-42 patient samples) may be a feasible number as staff build proficiency.

ORDER SIZES

- 1 Extraction Kit (90 extractions) and 1 Detection Kit (96 tests) provide the appropriate number of reagents for testing 84 patient samples, when batch sizes are maximized (6 cycles testing 14 patient samples each)[1].
- The annual number of kits that would be used in 1 year (260 working days) under different scenarios of batch efficiency and cycles per day is provided in Table 1.



Additional resources - Diagnostic Order Tool

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GDF TB Diagnostics Product categories

Please click any category to view the full product specifications

1. DETECTION AND RESISTANCE OF MTB	1.1 MOLECULAR TESTING: POC / NEAR-POC	1.1.1 Truenat MTB equipment
		1.1.2 Truenat MTB reagents
		1.1.3 Truenat consumables
		1.1.4 Truenat services
		1.1.5 TB-LAMP equipment
		1.1.6 TB-LAMP reagents
		1.1.7 TB-LAMP consumables
		1.1.8 TB-LAMP services
		1.1.10 GeneXpert Equipment (10 color)
		1.1.11 GeneXpert Satellite (10 color)
		1.1.12 GeneXpert reagents (6 and 10 color)
		1.1.13 GeneXpert consumables (6 and 10 color)
		1.1.14 GeneXpert services (same for 6 and 10 color)
	1.2 RAPID ANTIGEN DETECTION	

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GDF TB Medical devices Product categories

Please click any category to view the full product specifications

1. TB SCREENING / TRIAGE	1.1 CHEST RADIOGRAPHY (CXR)	1.1.1 Ultraportable Digital X-ray systems
	1.2 CAD TECHNOLOGIES	1.2.1 CAD software for automated interpretation of CXRs
	1.3 ACCESSORIES	1.3.1 Solar panel for Delft light and CAD4TB box

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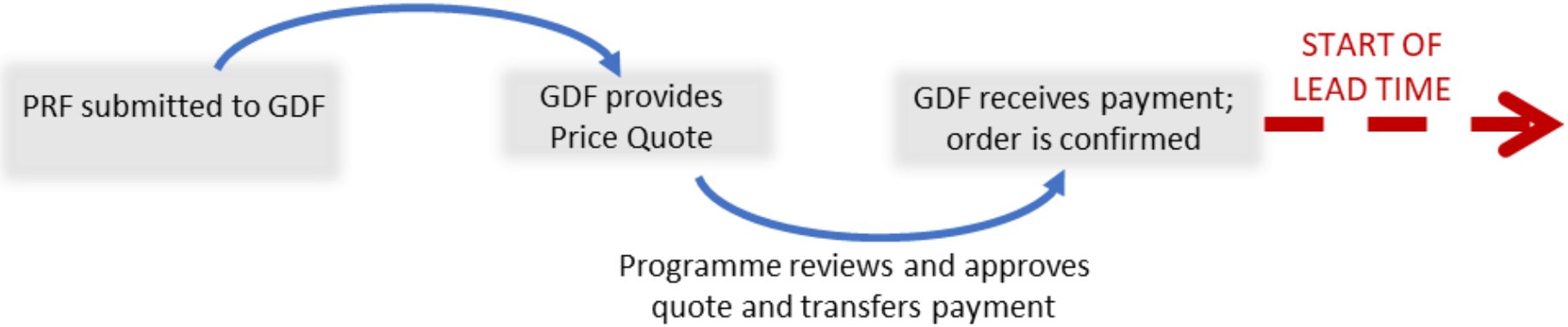
GDF TB Diagnostics Ordering List
Q2, 2021

GDF code	Product Name	Pack size	Min / max	Product technical specifications	Supplier	Supplier Lead Time	Quantity to order	Product price: Indicative CFA	Currency	Total Cost	Product transport type and packaging: Transport type	Weight Kg	Depth cm	Width cm	Height cm	Volume m3	Total Vol	Product in: Manufacturer product code
1. DETECTION OF MTB																		
1.1 MOLECULAR TESTING: POC / NEAR-POC																		
1.1.1 Truenat MTB equipment																		
166335	Truelab Duo Dell Workstation	1 set	0/10	Truelab Duo Time-Resolution micro PCR Engine to run 18-48 samples / 8 hours. The instrument accepts 18 results from the date of installation. This line includes: 1 Truelab Duo Dual Time-Resolution micro PCR Analyzer ([illegible]); 1 Transport ADTV-2 Universal Cartridge-based sample prep device ([illegible]); 1 Truelab micro PCR Printer ([illegible]); 1 Transport SOP-0 Fluid volume precision micropipette 4 µl ([illegible]); 1 Fold-over screen ([illegible]) and Accessories required for the equipment	Molbio Diagnostics	Barcelo		10000,00	USD	$	-	General Cargo	11	44	33	38	0,11	-	[illegible]
166336	Truelab Duo Workstation	1 set	0/10	Truelab Duo Time-Resolution micro PCR Engine to run 18-48 samples / 8 hours. The instrument accepts 18 results from the date of installation. This line includes: 1 Truelab Duo Dual Time-Resolution micro PCR Analyzer ([illegible]); 1 Transport ADTV-2 Universal Cartridge-based sample prep device ([illegible]); 1 Truelab micro PCR Printer ([illegible]); 1 Transport SOP-0 Fluid volume precision micropipette 4 µl ([illegible]); 1 Fold-over screen ([illegible]) and Accessories required for the equipment	Molbio Diagnostics	Barcelo		10000,00	USD	$	-	General Cargo	11	44	33	38	0,11	-	[illegible]
166337	Truelab Duo Mini Workstation	1 set	0/10	Truelab Duo Time-Resolution micro PCR Engine to run 12-48 samples / 8 hours. The instrument accepts 12 results from the date of installation. This line includes: 1 Truelab Duo Dual Time-Resolution micro PCR Analyzer ([illegible]); 2 Transport ADTV-2 Universal Cartridge-based sample prep device ([illegible]); 1 Truelab micro PCR Printer ([illegible]); 1 Transport SOP-0 Fluid volume precision micropipette 4 µl ([illegible]); 1 Fold-over screen ([illegible]) and Accessories required for the equipment	Molbio Diagnostics	Barcelo		10000,00	USD	$	-	General Cargo	22	33	104	34	0,100	-	[illegible]
1.1.2 Truenat MTB reagents																		
166332	Truenat MTB - 37	3 kits	12-24 months	Chip-based Real Time-PCR kit for Mycobacterium tuberculosis. Assay based on Taqman chemistry with animal sample requirement (2 µL). This line includes: A. Individually packed pouches with Truenat MTB micro PCR chip (Manufacturer with former brand PCR cocktail); 50 mm Diffuser tip pipette tip and Disposal pouch B. Transport ADTV Universal Cartridge Based Sample Prep Kit - 37 kits. C. Transport ADTV MTB Sample Pre-Incubated Pouch (Sample pre-incubated pouch for MTB samples) - 37 D. Package insert(s) Furthermore, 100 Truenat MTB tests are free, 200 Truenat MTB RIF tests will be included in the order free of charge. 10 pcs are eligible for the MTB RIF free of charge, please add the 200 of MTB RIF for free using the MTB-RIF-Sample with "zero" value.	Molbio Diagnostics	Barcelo		45,00	USD	$	-	General Cargo	10,00	0,5	7,5	37	0,07	-	[illegible]
166333	Truenat MTB - 37 T	20 kits	12-24 months	Chip-based Real Time-PCR kit for Mycobacterium tuberculosis. Assay based on Taqman chemistry with animal sample requirement (2 µL). This line includes: A. Individually packed pouches with Truenat MTB micro PCR chip (Manufacturer with former brand PCR cocktail); 50 mm Diffuser tip pipette tip and Disposal pouch; B. Transport ADTV Universal Cartridge Based Sample Prep Kit - 37 T; C. Transport ADTV MTB Sample Pre-Incubated Pouch (Sample pre-incubated pouch for MTB samples) - 37 T;	Molbio Diagnostics	Barcelo		180,00	USD	$	-	General cargo	10,00	0,5	7,5	37	0,25	-	[illegible]

- Facilitates order planning by providing product specifications, shipment logistics and automating costing

GDF lead times for Diagnostics, medical devices and health products

Standard lead times vary from 4 - 6 months after the payment/confirmation of the order which comprises production, QC, pre-shipment inspection, internal processing, and transport to the destination.



In the context of COVID-19 impacts on the supply chain including increased international air and ocean freight capacity constraints, clients are encouraged to place orders earlier than ordinarily to compensate for these constraints.

Take Home Points

- More than 500 diagnostics products, diagnostic devices and reagents, together with the consumables for all levels of laboratories are available in the GDF catalogue at the best prices and access terms: UN General Assembly declaration encourages all nations to use StopTB GDF for procurement
- Available online resources and tools from the StopTB Partnership website support countries in ordering diagnostics, medical devices and other health products procurement and during funding proposals and grant-making.
- TB programs should place procurement orders as early as possible, considering lead times that are affected by COVID-19 impacts on the SC, including increased international air and ocean freight capacity constraints.

Thank you!

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