

▶▶ INTRODUCING



# Truenat<sup>®</sup>

A Rapid Molecular Diagnostic for Use at Peripheral Health Facilities and Community Settings



**USAID**  
FROM THE AMERICAN PEOPLE

Stop **TB** Partnership





▶▶ **What is Truenat®?**

Truenat® is a rapid molecular diagnostic platform that can be completely laboratory independent with portable, battery-operated equipment and room temperature stable (2°C to 30°C), ready-to-use reagents. The platform enables health care set ups including remote and resource-limited settings to conduct sophisticated NAAT testing for multiple diseases including TB and MDR-TB.

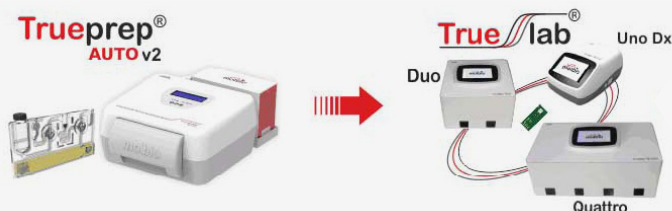
▶▶ **Where can Truenat® systems be positioned?**

Truenat® MTB, Truenat® MTB Plus and Truenat® MTB-RIF are recommended by the WHO as initial tests to detect TB (i.e., replacing sputum smear microscopy) and to subsequently detect rifampicin resistance. Truenat® can be positioned across all levels of a diagnostic network including primary and community healthcare centers, field hospitals and clinics, mobile testing units, health camps, prisons, etc.

▶▶ **How does the Truenat® system work?**

Truenat® has a simple workflow. The sputum sample is liquified and added to lysis buffer. The extraction happens in 20 minutes using the Cartridge based Trueprep® AUTO device. A small portion of the extracted nucleic acids is loaded on to the Truenat chip that runs on the Truelab® Real Time micro PCR Analyzer. Results are displayed automatically within 40 minutes (rifampicin resistance testing for MTB positive samples requires an additional hour). These are stored on the instrument and can be printed or transferred through wired or wireless options. All reagents and consumables are provided with the kit.

▶▶ **Truenat® Real Time Quantitative micro PCR System**  
**Sample to results in less than 1 Hour**



## ▶▶ What is the throughput of the Truenat® systems?

Workstation	Maximum Throughput (per 8 hrs)	Throughput with "real-world" conditions	Comments
Truelab® Uno Dx	10 - 12 samples	7 - 9 samples	Single testing bay
Truelab® Duo	20 - 24 samples	15 - 18 samples	2 bays: Independently running tests
Truelab® Quattro	40 - 48 samples	30 - 36 samples	4 bays: Independently running tests

## ▶▶ Truenat's global impact

In spite of WHO guidelines of replacing microscopy with a molecular test, most high burden countries are still relying heavily on sputum microscopy as the mainstay for TB diagnosis. This is because of lack of access to molecular tools that can be placed at peripheral health facilities and used in community settings. Truenat would enable bridging this gap and providing the much required last mile access. This can ensure same day diagnosis and treatment initiation at the first point of contact.

A collaboration with the Global Fund, USAID and Stop TB Partnership aims at expanding equitable access to quality TB rapid testing in underserved populations through globally negotiated Truenat® MTB / Truenat® MTB Plus pricing of US\$ 7.9 per test. The price includes the follow-on rifampicin resistance Truenat® MTB-RIF test for positive cases (20% of TB test supplies) and a package of services to ensure trouble-free operations.



## ▶▶ ORDERING INFORMATION

### ▶▶ Hardware

Workstation	Components	Price
Truelab® Uno Dx	1 x Truelab® Uno Dx Real Time Quantitative micro PCR Analyzer	10,000 US\$
	1 x Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device	
	Installation and training	500 US\$
Truelab® Duo	1 x Truelab® Duo Real Time Quantitative micro PCR Analyzer	14,000 US\$
	1 x Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device	
	Installation and training	500 US\$
Truelab® Quattro	1 x Truelab® Quattro Real Time Quantitative micro PCR Analyzer	18,000 US\$
	2 x Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device	
	Installation and training	500 US\$

### ▶▶ Reagents

Test	Components	Price
Truenat® MTB / MTB Plus	Trueprep® AUTO MTB Sample Pre-treatment Pack (20, 25 or 50 test pack)	7.9 US\$
	Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit (50 test pack)	
	Truenat® MTB/MTB Plus Chip-based Real Time PCR test for MTB (5, 25 or 50 test pack)	
	Truenat® MTB-RIF Dx chip-based Real Time PCR test for rifampicin resistance*	

\*Truenat® MTB-RIF Dx is a follow-on test to be performed ONLY in TB positive cases. 20% of the number of Truenat® MTB / MTB Plus tests ordered at provided free-of-cost. Quantity above 20% may be purchased at US\$ 8/test.

### ▶▶ Example order for 500 tests of Truenat® MTB / MTB Plus

Test Components	Nos.
Truenat® MTB / MTB Plus	500
Truenat® MTB-RIF Dx (20% free-of-cost)	100
Trueprep® AUTO MTB Sample Pre-treatment Pack	500
Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	500
Positive Control Panel (8 Test Pack) - free-of-cost*	01

\*Additional Positive Control Panels may be procured for US\$ 8 each.



### ▶▶ **Molbio's service commitments**

All Truenat workstations come with initial 1-year warranties, with the possibility to buy annual warranty extensions at a cost of US\$ 1,120 per workstation per year. All warranties provide comprehensive service and maintenance, including repair and replacement of parts and equipment, plus on-site visits as required.

#### **Molbio undertakes the following service commitments:**

- Committed to maintain  $\geq 95\%$  of the number of installed Truenat devices in complete working condition whensoever.
- Committed to execute repairs and provide replacements within 10 working days for  $\geq 90\%$  of occurrences.
- Committed to respond to customer service requests with a follow-up plan articulated within  $\leq 2$  working days for  $\geq 95\%$  of incidences.

▶▶ **For more information on the products, please visit [www.molbiodiagnostics.com](http://www.molbiodiagnostics.com)**

▶▶ **For more information on ordering, please visit the [Stop TB Partnership GDF product catalog](#)**

▶▶ **For additional resources, including training modules, practical guidance and country case studies, please visit [www.stoptb.org/accelerate-tb-innovations/introducing-new-tools-project](http://www.stoptb.org/accelerate-tb-innovations/introducing-new-tools-project)**

