



Date: 27.06.2025

MTB/MDR-TB detection kits prospectively validated and approved by ICMR

Please Note:

- The kits listed below are validated with the model and lot/batch numbers only as mentioned and for the specified scope of the test kit.
- Responsibility for use in any other model or batch to batch consistency does not lie with ICMR.
- ICMR validation is not a pre-requisite for DCGI approval.
- ICMR validation does not guarantee that the kit will be included in ICMR tenders.
- Kits validated on stored samples have not been included in this list.

Till date, the following molecular assays have been found to be satisfactory for detection of MTB only or MTB and MDR-TB

S. No	Name of company	Name of the kit	Lot / Batch No./Model	Sample used for validation	Scope of the Validated Test kit
Closed PCR Systems (can be run only in the specific platform)					
1.	Molbio Diagnostics Pvt. Ltd., Verna Goa, India	Truenat MTB and Truenat MTB-RIF Dx	Truelab™ Uno (V1.5) analyzer	Sputum	MTB & MTB-RIF <ul style="list-style-type: none"> Adult PTB (2018) Paediatric TB & EPTB (2021)
2.	MyLab Discovery Solutions Pvt. Ltd., Pune, Maharashtra, India	PathoDetect™ MTB RIF and INH	CP00005-L-1221001E to L-1221005E (Compact XL/Compact Q Platform)	Sputum	MTB & MTB-RIF/INH <ul style="list-style-type: none"> Adult PTB (2022)
Open PCR systems					
3.	Huwei lifesciences Pvt. Ltd., Sangareddy District, Telangana	Quantiplus® MTB FAST Detection Kit PI/QLFMTB-03 (version-2) (with three gene targets only)	<ul style="list-style-type: none"> Quick Lysis buffer Lot No: HLQLB2403 Huwei Quantiplus MTB Fast detection PCR Kit Lot No: QLFMTB2409 	Sputum	MTB only <ul style="list-style-type: none"> Adult PTB (2025)
Point of Care (POC) tests					
4.	Huwei lifesciences Pvt. Ltd., Sangareddy District, Telangana	UniAMP® MTB nucleic acid test card	Batch No: PQLMTB2422 PQLMTB2414	Sputum swab	MTB only Adult PTB (2025)
		1. Sputum swab PCR kit (software version 4.2.4)			
		2. Tongue swab PCR kit (software version 4.2.1)	Batch No: PQLMTB2422 PQLMTB2414	Tongue swab	MTB only Adult PTB (2025)