



Date: 14.02.2025

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

Please Note:

- Below listed kits are validated with the mentioned model and lot/batch numbers only as per specified scope of the test kit.
- Responsibility for use in other model or batch to batch consistency does not lie with ICMR.
- ICMR validation is not 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 three molecular assays have been found to be satisfactory for detection of 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.	Huwel 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• Huwel Quantiplus MTB Fast detection PCR Kit Lot No: QLFMTB2409	Sputum	MTB only <ul style="list-style-type: none">• Adult PTB (2025)