



Date: 24.05.2023

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 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, two molecular assays have been validated by ICMR and both are 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 Test kit validated
1.	Molbio Diagnostics Pvt. Ltd., Verna (Goa), India	Truenat MTB and Truenat MTB-RIF Dx	- (Truelab™ Uno (V1.5) analyzer)	Sputum	<ul style="list-style-type: none">• MTB• MTB RIF• Adult PTB (2018)• Paediatric TB & EPTB (2021)
2.	MyLab Discovery Solutions Pvt. Ltd., Pune (Maharashtra), India	PathoDetect™ MTB RIF and INH	CP00005-L-1221001E CP00005-L-1221002E CP00005-L-1221003E CP00005-L-1221004E CP00005-L-1221005E (Compact XL/Compact Q Platform)	Sputum	<ul style="list-style-type: none">• MTB• MTB RIF & INH• Adult PTB (2022)