

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Licence no.: MFG/IVD/2025/000148

Date: 15/03/2026
Document ID: COA/TN/PCI062

Product Name	Truenat [®] Positive Control Kit - Panel I
Generic Name	Control Kit for Truenat [®] Chip-based micro PCR Tests: MTB, MTB Plus, MTB-RIF Dx, Beta CoV, SARS CoV-2, COVID-19 and H1N1
Lot No.	PCI062
Mfg. Date	2026-03
Exp. Date	2027-02
Pack Size	08T
Storage condition	2°C to 40°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Negative control	Should be present	Present
02	Positive control (08- strip tubes containing dried down positive control)	Should be present	Present
03	Package insert	Should be present	Present

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Performance testing data			
Sr. No.	Truenat [®] test name	Positive control	Negative control
1	MTB	30.42 ± 0.82	ND
2	MTB Plus	29.03 ± 0.58	ND
3	MTB-RIF Dx	RIF Resistance detected	Indeterminate
4	SARS CoV-2	28.23 ± 0.57	ND
5	COVID-19	Orf 1A: 27.38 ± 0.53 E gene: 26.83 ± 0.48	ND
6	H1N1	28.19 ± 0.61	ND

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC standards and is approved



for
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Department: Quality Control
Designation: QC Head