

MOLBIO DIAGNOSTICS LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Licence no.: MFG/IVD/2019/000003

Date: 11/09/2026
Document ID: COA/TN/PCI071

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.	PCI071
Mfg. Date	2026-09
Exp. Date	2027-08
Pack Size	8T
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

Performance testing data			
Sr. No.	Truenat [®] test name	Positive control	Negative control
1	MTB	30.78 ± 0.84	ND
2	MTB Plus	28.65 ± 1.26	ND
3	MTB-RIF Dx	RIF Resistance detected	Indeterminate
4	SARS CoV-2	28.35 ± 0.35	ND
5	COVID-19	Orf 1A: 26.63 ± 0.26 E gene: 28.47 ± 0.54	ND
6	H1N1	28.02 ± 0.96	ND

*Mfg- Manufacturing, Exp- Expiry

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



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