

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

Licence no.: MFG/IVD/2025/000148

Date: 03/07/2026
Document ID: COA/TN/PCI068

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.	PCI068
Mfg. Date	2026-06
Exp. Date	2027-05
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	30.35 ± 0.39	ND
2	MTB Plus	29.47 ± 0.47	ND
3	MTB-RIF Dx	RIF Resistance detected	Indeterminate
4	SARS CoV-2	28.65 ± 0.26	ND
5	COVID-19	Orf 1A: 27.25 ± 0.27 E gene: 28.09 ± 0.52	ND
6	H1N1	27.93 ± 0.14	ND

*Mfg- Manufacturing, Exp- Expiry

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



for Name: Dr. Praveen Kumar MK
Department: Quality Control
Designation: QC Head