

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Licence no.: MFG/IVD/2025/000148

Date: 09/07/2026

Document ID: COA/TN/PC1069

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.	PC1069
Mfg. Date	2026-07
Exp. Date	2027-06
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	30.10 ± 0.72	ND
2	MTB Plus	27.15 ± 0.60	ND
3	MTB-RIF Dx	RIF Resistance detected	Indeterminate
4	SARS CoV-2	28.18 ± 0.33	ND
5	COVID-19	Orf 1A: 26.58 ± 0.69 E gene: 24.74 ± 0.41	ND
6	H1N1	26.64 ± 0.39	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