

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

Licence no.: MFG/IVD/2019/000003

Date: 05/06/2026
Document ID: COA/TN/PCI066

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.	PCI066
Mfg. Date	2026-05
Exp. Date	2027-04
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	30.67 ± 0.59	ND
2	MTB Plus	29.45 ± 0.24	ND
3	MTB-RIF Dx	RIF Resistance detected	Indeterminate
4	SARS CoV-2	27.72 ± 0.21	ND
5	COVID-19	Orf 1A: 26.68 ± 0.35 E gene: 26.46 ± 0.51	ND
6	H1N1	27.94 ± 0.19	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