

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

Licence no.: MFG/IVD/2019/000003

Date: 25/07/2026
Document ID: COA/TN/PCI070

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.	PCI070
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	30.53 ± 0.46	ND
2	MTB Plus	28.79 ± 0.23	ND
3	MTB-RIF Dx	RIF Resistance detected	Indeterminate
4	SARS CoV-2	27.41 ± 0.20	ND
5	COVID-19	Orf 1A: 27.74 ± 0.53 E gene: 26.21 ± 0.09	ND
6	H1N1	26.86 ± 0.28	ND

*Mfg- Manufacturing, Exp- Expiry

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



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