

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date: 18/12/2025

Doc ID: COA/TN/PCI057

BRAND 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	PCI057
MFG. DATE	2025-12
EXP. DATE	2026-11
PACK SIZE	08T
STORAGE	2°C to 40°C A.R. No. : B-PCI-057

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat [®] test name	Positive control	Negative control
1	MTB	26.83 ± 0.41	ND
2	MTB Plus	25.44 ± 0.34	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	27.49 ± 0.73	ND
5	COVID-19	Orf 1A: 27.13 ± 0.15 E gene: 26.65 ± 0.42	ND
6	H1N1	25.68 ± 0.43	ND

*ND- Not detected, Ct- Cycle threshold, RIF- Rifampicin, NA- Not Applicable

*A deviation of ≤1.5 is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE

QUALITY CONTROL

Name: Dr. Praveen Kumar MK

Designation: QC Head

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