

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 12/11/2025

Doc ID: COA/TN/PCI051

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	PCI051
MFG. DATE	2025-10
EXP. DATE	2026-09
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCI-051	

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	27.16 ± 0.14	ND
2	MTB Plus	25.63 ± 0.46	ND
3	MTB-RIF Dx	RIF Resistance detected	NA
4	SARS CoV-2	26.52 ± 0.91	ND
5	COVID-19	Orf 1A: 26.59 ± 0.27 E gene: 26.34 ± 0.47	ND
6	H1N1	26.86 ± 0.23	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 LOTS RELEASED FOR SALE

QUALITY CONTROL
Name: Dr. Praveen Kumar MK
Designation: QC Head

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