

MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 30/11/2024

Doc ID: COA/TN/PCI034

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	PCI034
MFG. DATE	2024-11
EXP. DATE	2025-10
PACK SIZE	08T
STORAGE	2°C to 40°C A.R. No. : B-PCI-034

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	24.61 ± 0.24	ND
2	MTB Plus	26.81 ± 0.25	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	25.48 ± 0.28	ND
5	COVID-19	Orf 1A: 26.27 ± 0.14 E gene: 26.86 ± 0.29	ND
6	H1N1	26.06 ± 0.10	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
 Designation: QC Head