

MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 11/12/2024
Doc ID: COA/TN/PCI035

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	PCI035
MFG. DATE	2024-11
EXP. DATE	2025-10
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCI-035	

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	27.59 ± 0.27	ND
2	MTB Plus	26.23 ± 0.10	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	29.08 ± 0.69	ND
5	COVID-19	Orf 1A: 26.05 ± 0.20 E gene: 27.24 ± 0.17	ND
6	H1N1	26.18 ± 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
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Designation: QC Head