

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/11/2025

Doc ID: COA/TN/PCI056

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	PCI056	
MFG. DATE	2025-11	
EXP. DATE	2026-10	
PACK SIZE	08T	
STORAGE	2°C to 40°C	A.R. No. : B-PCI-056

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	26.82 ± 0.43	ND
2	MTB Plus	25.93 ± 0.23	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	27.88 ± 0.69	ND
5	COVID-19	Orf 1A: 27.92 ± 0.53 E gene: 28.88 ± 0.33	ND
6	H1N1	27.83 ± 0.85	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

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