

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 10/02/2026
Doc ID: COA/TN/PCI060

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	PCI060		
MFG. DATE	2026-02		
EXP. DATE	2027-01		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No. : 40000046366	

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	28.81 ± 0.54	ND
2	MTB Plus	27.62 ± 0.42	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	28.25 ± 0.23	ND
5	COVID-19	Orf 1A: 28.23 ± 0.59 E gene: 27.63 ± 0.15	ND
6	H1N1	28.03 ± 0.38	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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