

MOLBIO DIAGNOSTICS LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date: 25/02/2026
Doc ID: COA/TN/PCI061

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	PCI061		
MFG. DATE	2026-02		
EXP. DATE	2027-01		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : 40000047190

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	30.31 ± 0.18	ND
2	MTB Plus	28.97 ± 0.45	ND
3	MTB-RIF Dx	RIF Resistance detected	NA
4	SARS CoV-2	28.39 ± 0.42	ND
5	COVID-19	Orf 1A: 28.77 ± 0.70 E gene: 28.38 ± 0.66	ND
6	H1N1	27.95 ± 0.54	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