

**MOLBIO DIAGNOSTICS LIMITED**

EN ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date: 28/05/2025

Doc ID: COA/TN/PCI040

BRAND NAME	Truenat <sup>®</sup> Positive Control Kit - Panel I
GENERIC NAME	Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: MTB, MTB Plus, MTB-RIF Dx, Beta CoV, SARS CoV-2, COVID-19 and H1N1
LOT NO	PCI040
MFG. DATE	2025-05
EXP. DATE	2026-04
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCI-040	

**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 <sup>®</sup> test name	Positive control	Negative control
1	MTB	27.42 ± 0.09	ND
2	MTB Plus	26.93 ± 0.28	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	27.03 ± 0.29	ND
5	COVID-19	Orf 1A: 25.57 ± 0.15 E gene: 27.68 ± 0.21	ND
6	H1N1	27.62 ± 0.35	ND

\*ND- Not detected, Ct- Cycle threshold, RIF- Rifampicin, NA- Not Applicable

\*A deviation of  $\leq 1.5$  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**

*for*   
**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
Designation: QC Head