

Molbio Diagnostics Limited

(Formerly Molbio Diagnostics Private Limited) L-46, Phase II D, Verna Industrial Estate Verna, Goa-403722, India 3+918326724888 www.molbiodiagnostics.com

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/PCI041

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	PCI041		
MFG. DATE	2025-05		
EXP. DATE	2026-04		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No. : B-PCI-041	

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	26.79 ± 0.57	ND			
2	MTB Plus	26.18 ± 0.17	ND			
3	MTB-RIF Dx	RIF Resistance not detected	NA			
4	SARS CoV-2	26.28 ± 0.68	ND			
5	COVID-19	Orf 1A: 25.74 ± 0.42 E gene: 27.57 ± 0.18	ND			
6	H1N1	27.34 ± 0.29	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 1000 MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AMPLOT IS RELEASED FOR SALE

> QUALITY CONTROL* Name: Dr. Prayeen Kumar **Designation: QC Head**