



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 22/02/2024
Doc ID: COA/TN/PCI025

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, SARS CoV-2, COVID-19 and H1N1		
LOT NO	PCI025		
MFG. DATE	2024-02		
EXP. DATE	2025-01		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCI-025

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	27.28 ± 0.25	ND
2	MTB Plus	26.28 ± 0.24	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	24.72 ± 0.63	ND
5	COVID-19	ORF 1A: 25.61 ± 0.36 E gene: 24.34 ± 0.43	ND
6	H1N1	26.11 ± 0.39	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
Designation: QC Head



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Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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