



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 24/08/2023
Doc ID: COA/TN/PCI021

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	PCI021		
MFG. DATE	2023-08		
EXP. DATE	2024-07		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCI-021

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	26.12± 1.09	ND
2	MTB Plus	25.84 ± 0.86	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	28.25± 0.68	ND
5	COVID-19	ORF 1A: 27.47 ± 0.54 E gene: 27.37 ± 0.15	ND
6	H1N1	27.08 ± 0.43	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
Page 1 of 1

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO