



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 05/04/2023
Doc ID: COA/TN/PCI018

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	PCI018		
MFG. DATE	2023-03		
EXP. DATE	2024-02		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCI-018

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

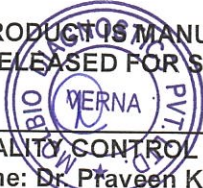
Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat® test name	Positive control	Negative control
1	MTB	26.95 ± 0.30	ND
2	MTB Plus	27.81 ± 0.21	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	27.32 ± 0.34	ND
5	COVID-19	ORF 1A: 27.91 ± 0.30 E gene: 26.35 ± 0.38	ND
6	H1N1	27.63 ± 0.36	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 PRODUCTS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE


QUALITY CONTROL
Name: Dr. Paveen Kumar
Designation: QC Head
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Molbio Diagnostics Private Limited

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