



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 12/04/2021
Doc ID: COA/TN/PCI003

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	PCI003
MFG. DATE	2021-03
EXP. DATE	2022-02
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCI-003	

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

Specification (Ct Value)				Observation (Ct Value)	
Sr. No.	Truenat™ test name	Positive control	Negative control	Positive control	Negative control
1	MTB	31.08 ± 2	ND	31.08	ND
2	MTB Plus	29.0 ± 2	ND	29.0	ND
3	MTB-RIF Dx	RIF Resistance not detected	Indeterminate	RIF Resistance not detected	Indeterminate
4	SARS CoV-2	29.11± 2	ND	29.11	ND
5	COVID-19	ORF1A: 27.83 ± 2; E gene: 29.0 ± 2	ND	ORF1A: 27.83 E gene: 29.0	ND
6	H1N1	27.25± 2	ND	27.25	ND

*ND- Not detected, Ct- Cycle threshold, RIF- Rifampicin

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
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Molbio Diagnostics Private Limited

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