



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 02/06/2022
Doc ID: COA/TN/PCI012

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	PCI012		
MFG. DATE	2022-05		
EXP. DATE	2023-04		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCI-012

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	29.51 ± 0.44	ND
2	MTB Plus	29.42 ± 0.59	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	26.23 ± 0.64	ND
5	COVID-19	ORF 1A: 28.20 ± 0.19 E gene: 28.81 ± 0.54	ND
6	H1N1	27.65 ± 0.37	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
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Designation: QC Head
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Molbio Diagnostics Private Limited

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