



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 11/10/2022  
Doc ID: COA/TN/PCI015

BRAND NAME	Truenat <sup>®</sup> Positive Control Kit - Panel I		
GENERIC NAME	Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: MTB, MTB Plus, MTB-RIF Dx, SARS CoV-2, COVID-19 and H1N1		
LOT NO	PCI015		
MFG. DATE	2022-10		
EXP. DATE	2023-09		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCI-015

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 <sup>®</sup> test name	Positive control	Negative control
1	MTB	27.74 ± 0.07	ND
2	MTB Plus	28.87 ± 0.39	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	28.31 ± 0.13	ND
5	COVID-19	ORF 1A: 29.13 ± 0.39 E gene: 28.65 ± 0.22	ND
6	H1N1	28.13 ± 0.70	ND

\*ND- Not detected, Ct- Cycle threshold, RIF- Rifampicin, NA- Not Applicable

\*A deviation of  $\leq 1.5$  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**

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO