

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date: 22/03/2025**

**Doc ID: COA/TN/PCI038**

<b>BRAND NAME</b>	Truenat <sup>®</sup> Positive Control Kit - Panel I
<b>GENERIC NAME</b>	Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: MTB, MTB Plus, MTB-RIF Dx, Beta CoV, SARS CoV-2, COVID-19 and H1N1
<b>LOT NO</b>	PCI038
<b>MFG. DATE</b>	2025-03
<b>EXP. DATE</b>	2026-02
<b>PACK SIZE</b>	08T
<b>STORAGE</b>	2°C to 40°C
<b>A.R. No. : B-PCI-038</b>	

**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	25.64 ± 0.13	ND
2	MTB Plus	25.87 ± 0.22	ND
3	MTB-RIF Dx	RIF Resistance not detected	NA
4	SARS CoV-2	27.00 ± 0.65	ND
5	COVID-19	Orf 1A: 26.77 ± 0.59 E gene: 27.09 ± 0.17	ND
6	H1N1	28.08 ± 0.14	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**

*for*  **GOA**  
**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
Designation: QC Head