



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 16/12/2022  
Doc ID: COA/TN/PCII010

BRAND NAME	Truenat® Positive Control Kit - Panel II
GENERIC NAME	Control Kit for Truenat® Chip-based micro PCR Tests: HBV, HCV, HIV-1, HLA-B27, Dengue, Chikungunya and Influenza A/B
LOT NO	PCII010
MFG. DATE	2022-12
EXP. DATE	2023-11
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCII-010	

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	HBV	28.04 ± 0.70	ND
2	HCV	27.69 ± 0.27	ND
3	HIV-1	28.88 ± 0.33	ND
4	HLA-B27	27.37 ± 0.17	ND
5	Dengue/ Chikungunya	Dengue : 26.30 ± 0.17 Chikungunya : 27.94 ± 0.29	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 28.32± 0.19 Influenza B : 27.50± 0.25	Influenza A : ND Influenza B : ND

\*ND- Not detected, Ct- Cycle threshold

\*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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