



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 20/09/2022  
Doc ID: COA/TN/PCII009

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	PCII009
MFG. DATE	2022-09
EXP. DATE	2023-08
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCII-009	

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	26.51 ± 0.77	ND
2	HCV	27.01 ± 0.38	ND
3	HIV-1	29.54 ± 0.24	ND
4	HLA-B27	29.16 ± 0.95	ND
5	Dengue/ Chikungunya	Dengue : 26.47 ± 0.61 Chikungunya : 26.18 ± 0.61	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 26.91± 0.28 Influenza B : 26.84± 0.15	Influenza A : ND Influenza B : ND

\*ND- Not detected, Ct- Cycle threshold

\*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

Name: Dr. Praveen Kumar

Designation: QC-Head

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**Molbio Diagnostics Private Limited**

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