



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 14/06/2022
Doc ID: COA/TN/PCII007

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	PCII007		
MFG. DATE	2022-06		
EXP. DATE	2023-05		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCII-007

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	29.61 ± 1.05	ND
2	HCV	28.18 ± 0.27	ND
3	HIV-1	29.54 ± 0.41	ND
4	HLA-B27	27.16 ± 0.14	ND
5	Dengue/ Chikungunya	Dengue : 27.04 ± 0.21 Chikungunya : 27.6 ± 0.30	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.94 ± 0.82 Influenza B : 28.31 ± 0.51	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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