



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 01/12/2021

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	PCII005		
MFG. DATE	2021-11		
EXP. DATE	2022-10		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCII-005

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	27.69 ± 0.50	ND
2	HCV	26.23 ± 0.08	ND
3	HIV-1	29.26 ± 0.43	ND
4	HLA-B27	27.13 ± 0.30	ND
5	Dengue/ Chikungunya	Dengue : 26.64 ± 0.12 Chikungunya : 27.51 ± 0.37	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 26.2 ± 0.34 Influenza B : 27.18 ± 0.66	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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