



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 24/11/2023
Doc ID: COA/TN/PCII018

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	PCII018
MFG. DATE	2023-12
EXP. DATE	2024-11
PACK SIZE	08 T
STORAGE	2°C to 40°C
A.R. No.: B-PCII-018	

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	27.11 ± 0.19	ND
2	HCV	26.41 ± 0.20	ND
3	HIV-1	27.80 ± 1.04	ND
4	HLA-B27	27.16 ± 0.30	ND
5	Dengue/ Chikungunya	Dengue : 26.99 ± 0.31 Chikungunya : 27.81 ± 0.71	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.38 ± 0.20 Influenza B : 27.64 ± 0.12	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

Molbio Diagnostics Private Limited

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