

MOLBIO DIAGNOSTICS LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 17/01/2024
Doc ID: COA/TN/PCII022

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	PCII022		
MFG. DATE	2025-01		
EXP. DATE	2025-12		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.: B-PCII-022	

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	27.78 ± 0.26	ND
2	HCV	27.54 ± 0.12	ND
3	HIV-1	27.73 ± 0.61	ND
4	HLA-B27	26.43 ± 0.12	ND
5	Dengue/ Chikungunya	Dengue : 27.32 ± 0.34 Chikungunya : 26.61 ± 0.35	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 24.13 ± 0.27 Influenza B : 28.65 ± 0.48	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