

MOLBIO DIAGNOSTICS LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 22/04/2025
Doc ID: COA/TN/PCII023

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	PCII023		
MFG. DATE	2025-04		
EXP. DATE	2026-03		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No.: B-PCII-023

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	25.89 ± 0.51	ND
2	HCV	27.21 ± 1.27	ND
3	HIV-1	27.89 ± 0.28	ND
4	HLA-B27	26.99 ± 0.69	ND
5	Dengue/ Chikungunya	Dengue : 28.47 ± 0.31 Chikungunya : 27.08 ± 0.14	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.84 ± 0.36 Influenza B : 28.38 ± 0.59	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

for 
GOA
QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head