

MOLBIO DIAGNOSTICS LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Licence no.: MFG/IVD/2025/000148

Date: 31/08/2026
Document ID: COA/TN/PCII029

Product 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.	PCII029
Mfg. Date	2026-08
Exp. Date	2027-07
Pack Size	8T
Storage condition	2°C to 40°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Negative control	Should be present	Present
02	Positive control (08- strip tubes containing dried down positive control)	Should be present	Present
03	Package insert	Should be present	Present

Performance testing data			
Sr. No.	Truenat [®] test name	Positive control	Negative control
1	HBV	29.48 ± 0.04	ND
2	HCV	26.55 ± 0.08	ND
3	HIV-1	27.19 ± 0.17	ND
4	HLA-B27	27.12 ± 0.25	ND
5	Dengue/Chikungunya	Dengue: 27.69 ± 0.34 Chikungunya: 27.89 ± 0.35	ND
6	Influenza A/B	Influenza A: 27.93 ± 0.24 Influenza B: 28.38 ± 0.21	ND

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC standards and is approved.

for  
Name: Dr. Praveen Kumar MK
Department: Quality Control
Designation: QC Head