

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

Licence no.: MFG/IVD/2025/000148

Date: 10/06/2026
Document ID: COA/TN/PCII028

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.	PCII028
Mfg. Date	2026-06
Exp. Date	2027-05
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	28.16 ± 0.65	ND
2	HCV	26.50 ± 0.20	ND
3	HIV-1	29.26 ± 0.37	ND
4	HLA-B27	28.09 ± 0.69	ND
5	Dengue/Chikungunya	Dengue: 27.44 ± 0.14 Chikungunya: 27.67 ± 0.32	ND
6	Influenza A/B	Influenza A: 26.92 ± 0.39 Influenza B: 28.39 ± 0.69	ND

*Mfg- Manufacturing, Exp- Expiry

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



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