

MOLBIO DIAGNOSTICS LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 15/09/2025

Doc ID: COA/TN/PCII025

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	PCII025
MFG. DATE	2025-09
EXP. DATE	2026-08
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No.: B-PCII-025	

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	27.12 ± 0.80	ND
2	HCV	28.41 ± 0.14	ND
3	HIV-1	27.32 ± 0.32	ND
4	HLA-B27	27.46 ± 0.44	ND
5	Dengue/ Chikungunya	Dengue : 25.72 ± 0.37 Chikungunya : 27.98 ± 0.11	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.49 ± 0.45 Influenza B : 27.19 ± 0.37	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

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Designation: QC-Head

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