

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 01/12/2025

Doc ID: COA/TN/PCII027

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	PCII027
MFG. DATE	2025-11
EXP. DATE	2026-10
PACK SIZE	08T
STORAGE	2°C to 40°C A.R. No.: B-PCII-027

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	29.18 ± 0.47	ND
2	HCV	27.59 ± 0.27	ND
3	HIV-1	29.11 ± 0.10	ND
4	HLA-B27	27.97 ± 0.27	ND
5	Dengue/ Chikungunya	Dengue : 27.15 ± 0.15 Chikungunya : 27.86 ± 0.45	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 26.60 ± 0.59 Influenza B : 29.49 ± 0.73	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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