



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 24/11/2023
Doc ID: COA/TN/PCII017

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	PCII017
MFG. DATE	2023-11
EXP. DATE	2024-10
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No.: B-PCII-017	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

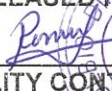
Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat® test name	Positive control	Negative control
1	HBV	27.40 ± 0.65	ND
2	HCV	26.02 ± 0.25	ND
3	HIV-1	26.98 ± 0.37	ND
4	HLA-B27	26.62 ± 0.13	ND
5	Dengue/ Chikungunya	Dengue : 25.19 ± 0.12 Chikungunya : 27.66 ± 0.48	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.70 ± 0.26 Influenza B : 28.52 ± 1.00	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


VERNA PVT. LTD.
QUALITY CONTROL
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Molbio Diagnostics Private Limited

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