



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 22/06/2023
Doc ID: COA/TN/PCII014

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	PCII014
MFG. DATE	2023-06
EXP. DATE	2024-05
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No.: B-PCII-014	

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	27.32 ± 0.47	ND
2	HCV	27.95 ± 0.22	ND
3	HIV-1	27.81 ± 0.42	ND
4	HLA-B27	28.12 ± 0.77	ND
5	Dengue/ Chikungunya	Dengue : 26.87 ± 0.29 Chikungunya : 28.42 ± 0.22	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.78 ± 0.31 Influenza B : 27.63 ± 0.50	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
Name: Dr. Praveen Kumar
Designation: QC Head

Page 1 of 1

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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