



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 25/10/2021

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, INFLUENZA A/B		
LOT NO	PCII003		
MFG. DATE	2021-10		
EXP. DATE	2022-09		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCII-003

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	27.7 ± 0.51	ND
2	HCV	27.47 ± 0.33	ND
3	HIV-1	29.3 ± 0.39	ND
4	HLA-B27	29.5 ± 0.36	ND
5	Dengue/ Chikungunya	Dengue : 28.9 ± 0.16 Chikungunya : 28.57 ± 0.47	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.9 ± 0.36 Influenza B : 28.4 ± 0.48	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
for Designation: QC Head
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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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO