



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 12/11/2024
Doc ID: COA/TN/PCII021

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	PCII021
MFG. DATE	2024-10
EXP. DATE	2025-09
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No.: B-PCII-021	

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	26.50 ± .1.09	ND
2	HCV	23.19 ± 0.13	ND
3	HIV-1	26.63 ± 0.20	ND
4	HLA-B27	26.47 ± 0.18	ND
5	Dengue/ Chikungunya	Dengue :25.98 ± 0.17 Chikungunya : 27.62 ± 0.63	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 25.64 ± 0.31 Influenza B : 27.43 ± 0.31	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



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