

MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 01/07/2022  
Doc ID: COA/TN/PCII008

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	PCII008		
MFG. DATE	2022-06		
EXP. DATE	2023-05		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCII-008

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	26.65 ± 0.36	ND
2	HCV	27.49 ± 0.25	ND
3	HIV-1	27.64 ± 0.38	ND
4	HLA-B27	28.20 ± 0.09	ND
5	Dengue/ Chikungunya	Dengue : 26.15 ± 0.35 Chikungunya : 27.45 ± 0.38	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.78± 0.20 Influenza B : 28.75 ± 0.065	Influenza A : ND Influenza B : ND

\*ND- Not detected, Ct- Cycle threshold

\*A deviation of  $\leq 1.5$  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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