



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 06/05/2021
Doc ID: COA/TN/PCII002

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	PCII002		
MFG. DATE	2021-04		
EXP. DATE	2022-03		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCII-002


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

Specification (Ct Value)				Observation (Ct Value)	
Sr. No.	Truenat™ test name	Positive control	Negative control	Positive control	Negative control
1	HBV	30.0± 2	ND	30.0	ND
2	HCV	29.23± 2	ND	29.23	ND
3	HIV-1	27.33± 2	ND	27.33	ND
4	HLA-B27	29.17± 2	ND	29.17	ND
5	Dengue/ Chikungunya	D:28.71± 2; C:27.67± 2	ND	D:28.71; C:27.67	ND
6	Influenza A/B	A:29.13± 2; B:29.43± 2	ND	A:29.13; B:29.43	ND

*ND- Not detected, Ct- Cycle threshold

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

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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO