



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

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

Date: 12/09/2023  
Doc ID: COA/TN/PCII015

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	PCII015		
MFG. DATE	2023-09		
EXP. DATE	2024-08		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No.: B-PCII-015

**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	27.69 ± 0.18	ND
2	HCV	28.87 ± 0.50	ND
3	HIV-1	27.66 ± 0.49	ND
4	HLA-B27	27.65 ± 1.20	ND
5	Dengue/ Chikungunya	Dengue : 27.29 ± 0.34 Chikungunya : 28.19 ± 0.57	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A : 27.46 ± 0.35 Influenza B : 28.91 ± 0.61	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**

  
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**Molbio Diagnostics Private Limited**

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