

MOLBIO DIAGNOSTICS LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 10/06/2025

Doc ID: COA/TN/PCII024

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	PCII024
MFG. DATE	2025-05
EXP. DATE	2026-04
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No.: B-PCII-024	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

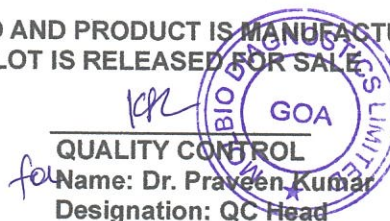
Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat [®] test name	Positive control	Negative control
1	HBV	27.11 ± 0.35	ND
2	HCV	27.37 ± 0.27	ND
3	HIV-1	28.33 ± 0.17	ND
4	HLA-B27	26.73 ± 0.31	ND
5	Dengue/ Chikungunya	Dengue :26.18 ± 0.47 Chikungunya : 27.96 ± 0.11	Dengue : ND Chikungunya : ND
6	Influenza A/B	Influenza A :26.16 ± 0.35 Influenza B : 29.59 ± 0.37	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

for  **GOA**
QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head