

MOLBIO DIAGNOSTICS LIMITED
EN ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date: 24/01/2025
Doc ID: COA/TN/PCV006

BRAND NAME	Truenat [®] Positive Control Kit - Panel V		
GENERIC NAME	Control Kit for Truenat [®] Chip-based micro PCR Tests: H3N2, Zika, Leish, Scrub T, Cholera and Shigella		
LOT NO	PCV006		
MFG. DATE	2025-01		
EXP. DATE	2025-12		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCV-006

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	H3N2	27.34 ± 0.97	ND
2	Zika	30.05 ± 0.08	ND
3	Leish	29.20 ± 0.44	ND
4	Scrub T	26.29 ± 0.25	ND
5	Cholera	28.17 ± 0.60	ND
6	Shigella	27.54 ± 0.19	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