



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

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

Date: 02/12/2023

Doc ID: COA/TN/PCV004

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	PCV004
MFG. DATE	2023-11
EXP. DATE	2024-10
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCV-004	

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	28.71 ± 0.37	ND
2	Zika	27.26 ± 0.22	ND
3	Leish	26.02 ± 0.85	ND
4	Scrub T	27.28 ± 0.19	ND
5	Cholera	27.04 ± 0.91	ND
6	Shigella	28.53 ± 0.32	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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