



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

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

Date: 06/07/2022
Doc ID: COA/TN/PCV005

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	PCV001
MFG. DATE	2022-06
EXP. DATE	2023-05
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCV-005	


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	29.49 ± 0.16	ND
2	Zika	26.94 ± 0.10	ND
3	Leish	27.71 ± 0.62	ND
4	Scrub T	28.01 ± 0.53	ND
5	Cholera	28.29 ± 0.19	ND
6	Shigella	29.47 ± 0.50	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
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Designation: QC Head
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Molbio Diagnostics Private Limited

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