



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 29/11/2023

Doc ID: COA/TN/PCIV009

BRAND NAME	Truenat® Positive Control Kit - Panel IV		
GENERIC NAME	Control Kit for Truenat® Chip-based micro PCR Tests: HAV, HEV, Rabies, LTS, Nipah and Malaria Pv/Pf		
LOT NO	PCIV009		
MFG. DATE	2023-11		
EXP. DATE	2024-10		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIV-009

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	HAV	26.50 ± 0.64	ND
2	HEV	27.05 ± 0.25	ND
3	Rabies	27.26 ± 0.50	ND
4	LTS	28.24 ± 0.37	ND
5	Nipah	27.11 ± 0.10	ND
6	Malaria Pv/Pf	Pv: 26.15 ± 0.17 Pf: 28.08 ± 0.30	Pv: ND Pf: 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

VERNA
QUALITY CONTROL
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Designation: QC Head

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Molbio Diagnostics Private Limited

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