

MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 11/12/2024

Doc ID: COA/TN/PCIV012

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	PCIV012
MFG. DATE	2024-11
EXP. DATE	2025-10
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCIV-012	

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	26.70 ± 0.63	ND
2	HEV	28.01 ± 0.35	ND
3	Rabies	27.47 ± 0.23	ND
4	LTS	26.95 ± 0.42	ND
5	Nipah	28.04 ± 0.06	ND
6	Malaria Pv/Pf	Pv: 27.53 ± 0.12 Pf: 24.65 ± 0.19	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

QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

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