

MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 28/12/2024

Doc ID: COA/TN/PCIV013

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	PCIV013		
MFG. DATE	2024-12		
EXP. DATE	2025-11		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIV-013

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	27.06 ± 0.10	ND
2	HEV	27.15 ± 0.64	ND
3	Rabies	29.48 ± 0.28	ND
4	LTS	27.85 ± 0.20	ND
5	Nipah	27.51 ± 0.35	ND
6	Malaria Pv/Pf	Pv: 27.72 ± 0.09 Pf: 26.76 ± 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

For 
QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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