

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 31/01/2025

Doc ID: COA/TN/PCIV014

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	PCIV014		
MFG. DATE	2025-01		
EXP. DATE	2025-12		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIV-014

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	26.79 ± 0.48	ND
2	HEV	26.99 ± 0.19	ND
3	Rabies	27.40 ± 0.22	ND
4	LTS	26.86 ± 0.48	ND
5	Nipah	27.71 ± 0.15	ND
6	Malaria Pv/Pf	Pv: 26.93 ± 0.12 Pf: 25.79 ± 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

Page 1 of 1