

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 25/04/2025

Doc ID: COA/TN/PCIV015

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	PCIV015
MFG. DATE	2025-04
EXP. DATE	2026-03
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCIV-015	

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	27.13 ± 0.12	ND
2	HEV	26.91 ± 0.18	ND
3	Rabies	27.78 ± 0.69	ND
4	LTS	29.01 ± 0.19	ND
5	Nipah	27.03 ± 0.25	ND
6	Malaria Pv/Pf	Pv: 26.82 ± 0.33 Pf: 27.18 ± 0.28	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