

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 09/06/2025

Doc ID: COA/TN/PCIV016

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	PCIV016
MFG. DATE	2025-05
EXP. DATE	2026-04
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCIV-016	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

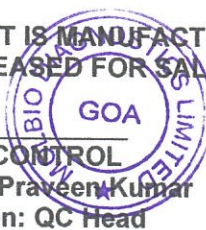
Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat [®] test name	Positive control	Negative control
1	HAV	26.51 ± 0.19	ND
2	HEV	26.52 ± 0.31	ND
3	Rabies	27.24 ± 0.32	ND
4	LTS	29.19 ± 0.59	ND
5	Nipah	27.14 ± 0.13	ND
6	Malaria Pv/Pf	Pv: 26.67 ± 0.29 Pf: 27.40 ± 0.57	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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