



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 30/03/2024

Doc ID: COA/TN/PCIV010

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	PCIV010		
MFG. DATE	2024-03		
EXP. DATE	2025-02		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIV-010

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

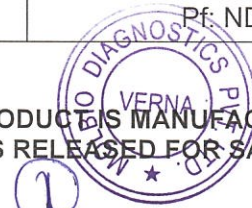
Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat® test name	Positive control	Negative control
1	HAV	26.99 ± 0.63	ND
2	HEV	28.01 ± 0.86	ND
3	Rabies	27.73 ± 0.30	ND
4	LTS	27.49 ± 0.28	ND
5	Nipah	27.02 ± 0.52	ND
6	Malaria Pv/Pf	Pv: 27.66 ± 0.46 Pf: 27.62 ± 0.17	Pv: ND Pf: ND

\*ND- Not detected, Ct- Cycle threshold

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCTS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE



QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

*for*

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## Molbio Diagnostics Private Limited

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