



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 06/09/2023

Doc ID: COA/TN/PCIV008

BRAND NAME	Truenat <sup>®</sup> Positive Control Kit - Panel IV		
GENERIC NAME	Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: HAV, HEV, Rabies, LTS, Nipah and Malaria Pv/Pf		
LOT NO	PCIV008		
MFG. DATE	2023-09		
EXP. DATE	2024-08		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIV-008

**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 <sup>®</sup> test name	Positive control	Negative control
1	HAV	27.03 ± 0.32	ND
2	HEV	28.21 ± 0.86	ND
3	Rabies	28.52 ± 0.31	ND
4	LTS	29.18 ± 0.82	ND
5	Nipah	26.89 ± 0.49	ND
6	Malaria Pv/Pf	Pv: 26.96 ± 0.20 Pf: 28.09 ± 0.08	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

**Molbio Diagnostics Private Limited**

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