



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 24/06/2022

Doc ID: COA/TN/PCIV005

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	PCIV005		
MFG. DATE	2022-06		
EXP. DATE	2023-05		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-PCIV-005

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	28.61± 0.54	ND
2	HEV	25.23± 0.25	ND
3	Rabies	29.12 ± 0.30	ND
4	LTS	30.21 ± 0.80	ND
5	Nipah	27.64± 0.19	ND
6	Malaria Pv/Pf	Pv:28.73 ± 0.48 Pf: 28.49 ± 0.23	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 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

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Molbio Diagnostics Private Limited

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