



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 01/09/2021

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	I-PCIV002		
MFG. DATE	2021-07		
EXP. DATE	2022-06		
PACK SIZE	08T		
STORAGE	2°C to 40°C	A.R. No.	: B-I-PCIV-002

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

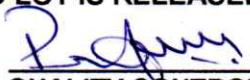
Sr. No.	Components in each kit	Specification	Observation
01	Negative control	Present	Present
02	Positive control (08- strip tubes containing dried down positive control)	Present	Present
03	Package insert	Present	Present

Observations (Ct Values)			
Sr. No.	Truenat <sup>®</sup> test name	Positive control	Negative control
01	HAV	28.51 ± 0.42	ND
02	HEV	29.76 ± 0.67	ND
03	Rabies	27.18 ± 0.07	ND
04	LTS	28.07 ± 0.16	ND
05	Nipah	27.58 ± 0.14	ND
06	Malaria Pv/Pf	Pv: 27.21 ± 0.03; Pf: 28.39 ± 0.36	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  
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Molbio Diagnostics Private Limited

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