



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 08/03/2022

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	PCIV004
MFG. DATE	2022-02
EXP. DATE	2023-01
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCIV-004	

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	27.53± 0.5	ND
2	HEV	28.30 ± 0.4	ND
3	Rabies	28.62 ± 0.05	ND
4	LTS	28.36 ± 0.7	ND
5	Nipah	28.16± 0.5	ND
6	Malaria Pv/Pf	Pv: 27.61 ± 0.1 Pf: 27.96 ± 0.4	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

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