



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000018

Date: 14/12/2021  
Doc. ID: COA/TN/HE008

BRAND NAME	Truenat® HEV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis E Virus
LOT No.	HE008
MFG. DATE	2021-09
EXP. DATE	2023-08
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C

A.R. No. : B-HE-008

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.


Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no, 50 nos	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
	HEV	Control
Specificity Tests		
Negative Control	ND	30
Positive Control	30.17	30.75
	28.75	30
	29.25	30
	29	30.2
Standard deviation	± 0.61	± 0.35

\*ND- Not detected, Ct- Cycle threshold, HEV- Hepatitis E Virus

\*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 QC APPROVED FOR SALE

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head  
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**Molbio Diagnostics Private Limited**

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