



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 21/12/2021

BRAND NAME	Truenat [®] HAV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis A Virus
LOT No.	HA010
MFG. DATE	2021-09
EXP. DATE	2023-08
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HA-010	

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 no	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HAV	Control
Negative Control	ND	27.4
Positive Control	29	28.6
	29	27.5
	28.29	28.13
	28.6	28.2
Standard deviation	± 0.34	± 0.45

*ND- Not detected, Ct- Cycle threshold, HAV- Hepatitis A Virus

*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 QC APPROVED FOR SALE


QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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