



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000040

Date:15/10/2022
Doc ID: COA/TN/HC043a

BRAND NAME	Truenat [®] HCV		
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis C Virus		
LOT No.	HC043	CHIP LOT NO.	HDLW480
MFG. DATE	2022-10	EXP. DATE	2024-09
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-HC-043a

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 dessicant pouch and 1 filter barrier tip	5 no, 20 no,25 no. 50 nos.	Pass
2	Color of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HCV	Control
Negative Control	ND	30.12
	ND	29.75
Positive Control	29.33	29.25
	29.23	29.44
	29.23	29.67
	29	29.06
	29.07	29.3
	29.31	29.2
	29.14	29.25
	29.89	29.33
Average	29.28	29.31
Standard deviation	±0.27	±0.18

*ND- Not detected, Ct- Cycle threshold, HCV- Hepatitis C 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

for Designation: QC Head

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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO