



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date: 29/10/2021
DOCID:COA/TN/HC035

BRAND NAME	Truenat [®] HCV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis C Virus
LOT No.	HC035
MFG. DATE	2021-11
EXP. DATE	2023-10
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HC-035	

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

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HCV	Control
Negative Control	ND	27.8
Positive Control	32	30.1
	31	30
	32	30.67
	31.55	30.75
Standard deviation	±0.47	± 0.38

*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
Designation: QC Head
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Molbio Diagnostics Private Limited

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