



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 13/03/2021

BRAND NAME	Truenat™ HCV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis C Virus
LOT No.	HC022
MFG. DATE	2020-12
EXP. DATE	2022-11
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HC-022	

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	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
	HCV	Control
Specificity Tests		
Negative Control	ND	30.14
Positive Control	29.64	29.64
	29	29.83
	29.07	30
	28.70	29.8
Standard deviation	± 0.39	± 0.24

*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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