



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

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

Date: 11-03-2020

BRAND NAME	Truenat™ HCV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis C Virus
LOT No.	HC013
MFG. DATE	2020- 02
EXP. DATE	2022- 01
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-HC-013	

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


PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HCV	Control
Negative Control	ND	27
	ND	27.14
Positive Control	29.88	27.43
	30.31	27
	29.5	26.8
	29.78	27.8
	29.6	26.6
	30.27	27.25
	29.67	27.14
	30.08	27.67
Standard deviation	± 0.30	± 0.34

*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 VERNA
Name: Dr. Praveen Kumar
Designation: QC Head
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