



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 07-02-2020

BRAND NAME	Truenat™ HCV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis C Virus
LOT No.	HC011
MFG. DATE	2020-01
EXP. DATE	2021-12
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-HC-011	

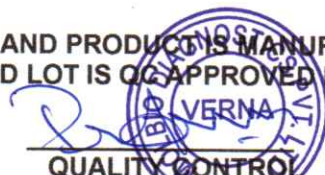
PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

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.	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	31.67
Positive Control	29.55	27.67
	30.0	28.8
	30.8	27.43
	29.07	28.13
Standard deviation	± 0.73	± 0.60

*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 PRODUCTS 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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