



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 11-12-2019

BRAND NAME :	:Truenat™ HCV
GENERIC NAME :	: Chip-based Real Time PCR Test for Hepatitis C Virus
LOT No.	: HC004
MFG. DATE	: 2019-11
EXP. DATE	: 2021- 10
PACK SIZE	: 5T, 20T
STORAGE	: 2°C to 30°C
A.R. No. : B-HC-004a	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

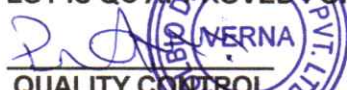
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HCV	Control
Negative Control	ND	27.67
Positive Control	29.31	28.43
	29.55	28.43
	30.23	30.0
	30.08	28.6
Standard deviation	± 0.43	± 0.76

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

\*A deviation of  $\leq 1.5$  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 Pvt. Ltd.**

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO