



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 07-03-2020

BRAND NAME	Truenat™ HCV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis C Virus
LOT No.	HC012
MFG. DATE	2020-02
EXP. DATE	2022-01
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-HC-012	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

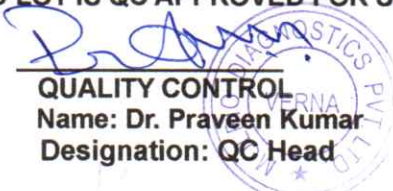
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	HCV	Control
Negative Control	ND	29.33
Positive Control	30.45	30.8
	29.33	30.2
	30.14	31.0
	30.7	29.5
Standard deviation	± 0.59	± 0.67

\*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:30AACCM8275E1Z0