



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 29-01-2020

BRAND NAME	Truenat™ HCV
GENERIC NAME	Chip-based Real Time PCR Test for Hepatitis C Virus
LOT No.	HC007
MFG. DATE	2019-12
EXP. DATE	2021-11
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-HC-007a	

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	31.17
Positive Control	29.07	29.0
	30.0	29.0
	29.25	29.0
	29.67	29.5
Standard deviation	± 0.41	± 0.25

*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 Pvt. Ltd.

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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