



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 Certified company

CERTIFICATE OF ANALYSIS

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

Date: 05-10-2019

PRODUCT : Truenat™ HCV
LOT NO. : HC001
MFG. DATE : 2019-09
EXP. DATE : 2021- 08
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. No. : B-HC-001a

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

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

Performance		
CONTROLS	Test Lot (Ct Values)	
	HCV	Control
Specificity Tests		
Negative Control	ND	29.71
Positive Control	29.45	30.33
	29.25	29.43
	30.5	29.5
	28.55	29.6
Standard deviation	± 0.80	± 0.41

*ND- Not detected

*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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