



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**ISO 13485:2016 certified company  
CERTIFICATE OF ANALYSIS**

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

**Date: 25/10/2021**

**DOCID:COA/TN/HC033**

<b>BRAND NAME</b>	Truenat® HCV	
<b>GENERIC NAME</b>	Chip-based Real Time PCR Test for Hepatitis C Virus	
<b>LOT No.</b>	HC033	
<b>MFG. DATE</b>	2021-10	
<b>EXP. DATE</b>	2023-09	
<b>PACK SIZE</b>	5T, 20T, 50T	
<b>STORAGE</b>	2°C to 30°C	<b>A.R. No. : B-HC-033</b>

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.


<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 50 no.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

<b>PERFORMANCE</b>		
<b>CONTROLS</b>	<b>(Ct Values)</b>	
<b>Specificity Tests</b>	<b>HCV</b>	<b>Control</b>
<b>Negative Control</b>	ND	30
	ND	30.5
<b>Positive Control</b>	28.88	29.5
	29.21	29.4
	27.78	29.57
	29.09	30.33
	28.2	29.6
	27.89	29.29
	29.33	29.33
<b>Standard deviation</b>	±0.60	± 0.35

\*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 Private Limited**

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO