



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

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

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

**Date: 16/10/2021**

**DOCID:COA/TN/HC032**

<b>BRAND NAME</b>	Truenat <sup>®</sup> HCV
<b>GENERIC NAME</b>	Chip-based Real Time PCR Test for Hepatitis C Virus
<b>LOT No.</b>	HC032
<b>MFG. DATE</b>	2021-09
<b>EXP. DATE</b>	2023-08
<b>PACK SIZE</b>	5T, 20T, 50T
<b>STORAGE</b>	2°C to 30°C

**A.R. No. : B-HC-032**

**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	28.2
	ND	28.75
<b>Positive Control</b>	27.14	27.5
	25.08	27.17
	26.55	26
	26.33	27.33
	25.7	26.67
	26.58	27.5
	25.0	25.33
<b>Standard deviation</b>	26.18	27
	±0.75	± 0.77

\*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:30AACCM8275E1Z0