



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date:06/06/2022**

**Doc ID: COA/TN/HC037**

<b>BRAND NAME</b>	<b>Truenat® HCV</b>		
<b>GENERIC NAME</b>	<b>Chip-based Real Time PCR Test for Hepatitis C Virus</b>		
<b>LOT No.</b>	<b>HC038</b>	<b>CHIP LOT NO.</b>	<b>HDLW411</b>
<b>MFG. DATE</b>	<b>2022-05</b>	<b>EXP. DATE</b>	<b>2024-04</b>
<b>PACK SIZE</b>	<b>5T, 20T, 25T, 50T</b>		
<b>STORAGE</b>	<b>2°C to 30°C</b>		<b>A.R. No.:B-HC-038/a</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,25 no. 50 nos.	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	27.2
	ND	27.8
<b>Positive Control</b>	30.14	28.38
	30.54	29.23
	28.7	28.11
	29.7	27.86
	28.7	27.57
	30.7	29.33
	29.25	28.56
	30.38	28.18
<b>Average</b>	29.76	28.4
<b>Standard deviation</b>	±0.80	±0.62

\*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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