



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**  
**EN ISO 13485:2016 certified company**  
**CERTIFICATE OF ANALYSIS**

Licence no.: MFG/IVD/2021/000071

Date: 29/08/2024

Document ID:COA/TN/013HCa/25T

|                   |   |
|-------------------|---|
| Product Name      | Truenat <sup>®</sup> HCV                            |
| Generic Name      | Chip-based Real Time PCR Test for Hepatitis C Virus |
| Lot No.           | 013HC   |
| Set No            | a   |
| Mfg. Date         | 2024-06   |
| Exp. Date         | 2026-05   |
| Pack Size         | 25T   |
| Storage condition | 2°C to 30°C   |

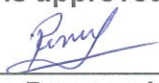

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

| Sr. No. | Components in each kit   | Specification                          | Observation             |
|---------|--|--|-------------------------|
| 01      | Number of pouches as per pack size   | Should be present                      | Present                 |
| 02      | Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip | Should be present                      | Present                 |
| 03      | Colour of desiccant pouch  | Should be present and Orange in Colour | Present / Orange Colour |
| 04      | Package Insert   | Should be present                      | Present                 |
| 05      | Seal integrity test  | Should pass                            | Pass                    |

| Performance testing data               |              |              |
|--|--------------|--------------|
| Samples                                | Ct Values    |              |
|  | HCV          | Control      |
| Non Template Control                   | ND           | ND           |
| Negative Sample                        | ND           | 29.09 ± 0.79 |
| Positive sample 1                      | 31.66 ± 0.58 | 26.79 ± 0.41 |
| Positive sample 2                      | 29.32 ± 0.58 | 27.88 ± 0.27 |
| Positive Sample 3                      | 22.01 ± 0.62 | 28.03 ± 0.75 |
| ND – Not detected, Ct- Cycle threshold |              |              |

\*Mfg- Manufacturing, Exp- Expiry

**The lot is tested and verified as per QC standards and is approved.**

  
Name : Dr. Praveen Kumar  
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