

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

Licence No.: MFG/IVD/2021/000071

Date: 06/05/2025

Document ID: COA/TN/019HC/25T

|                   |                                                     |
|-------------------|-----------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> HCV                            |
| Generic Name      | Chip-based Real Time PCR Test for Hepatitis C Virus |
| Lot No.           | 019HC                                               |
| Set No.           | NA                                                  |
| Mfg. Date         | 2025-03                                             |
| Exp. Date         | 2027-02                                             |
| 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      | Pouch 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           | 27.75 ± 0.59 |
| Positive sample 1        | 29.58 ± 0.85 | 27.40 ± 0.58 |
| Positive sample 2        | 23.27 ± 0.40 | 28.13 ± 0.31 |
| Positive Sample 3        | 26.42 ± 0.33 | 28.92 ± 0.58 |

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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Designation: QC Head

