

Licence no.: MFG/IVD/2021/000071

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| uct Name Truenat® HCV | |
| Chip-based Real Time PCR Test for Hepatitis C Virus | |
| 009HC | |
| а | |
| 2023-12 | |
| 2025-11 | |
| 5T, 25T | |
| 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 | | | | |
|--|--------------|--------------|--|--|
| | Ct Values | | | |
| Samples | HCV | Control | | |
| Non Template Control | ND | ND | | |
| Negative Sample | ND | 29.81 ± 0.77 | | |
| Positive sample 1 | 22.96 ± 0.45 | 27.38 ± 0.41 | | |
| Positive sample 2 | 27.40 ± 0.31 | 29.76 ± 0.66 | | |
| Positive Sample 3 | 30.45 ± 0.35 | 28.69 ± 0.32 | | |
| ND - Not detected, Ct- Cycle threshold | | | | |

*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices

Manufacturing records are verified, checked and product is manufactured as per the

GMP, samples tested and lot is QC approved for sale purpose.

Name : Dr. Praveen Kuman A Department: Quality Control

Designation: QC Head

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