



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 30/09/2020

| | |
|---------------------|---|
| BRAND NAME | Truenat™ HCV |
| GENERIC NAME | Chip-based Real Time PCR Test for Hepatitis C Virus |
| LOT No. | HC019 |
| MFG. DATE | 2020-09 |
| EXP. DATE | 2022-08 |
| PACK SIZE | 5T, 20T |
| STORAGE | 2°C to 30°C |
| A.R. No. : B-HC-019 | |

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

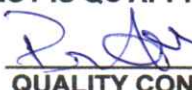
| Sr. No. | Components in each kit | Specification | Observation |
|---------|---|---------------|-------------|
| 1 | Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip | 5 no, 20 no. | Pass |
| 2 | Colour of desiccant pouch | Blue | Pass |
| 3 | Package insert | 01 no. | Pass |

| PERFORMANCE | | |
|--------------------|-------------|---------|
| CONTROLS | (Ct Values) | |
| Specificity Tests | HCV | Control |
| Negative Control | ND | 28.80 |
| | ND | 29 |
| Positive Control | 30.5 | 30.6 |
| | 30.55 | 30.43 |
| | 31.45 | 31 |
| | 30.73 | 30.75 |
| | 29.88 | 30.17 |
| | 29.4 | 29.75 |
| | 30.08 | 31 |
| | 29.23 | 29.57 |
| Standard deviation | ± 0.71 | ± 0.54 |

*ND- Not detected, Ct- Cycle threshold, HCV- Hepatitis C Virus

*A deviation of ≤ 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

Page 1 of 1

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO