



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

Licence no.: MFG/IVD/2019/000018

Date: 13/12/2023

Document ID: COA/TN/HE012a

| | |
|-------------------|--|
| Product Name | Truenat® HEV |
| Generic Name | Chip-based Real Time PCR Test for <i>Hepatitis E virus</i> |
| Lot No. | HE012 |
| Set No. | a |
| Mfg. Date | 2023-11 |
| Exp. Date | 2025-10 |
| Pack Size | 5T, 20T, 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 | |
| | HEV | Control |
| Non Template Control | ND | ND |
| Negative Sample | ND | 28.32 ± 0.38 |
| Positive sample 1 | 23.15 ± 0.38 | 27.70 ± 0.96 |
| Positive sample 2 | 25.46 ± 0.18 | 28.04 ± 0.65 |
| Positive Sample 3 | 30.31 ± 1.46 | 27.76 ± 1.37 |

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 Kumar
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FM/QT/219-01

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Molbio Diagnostics Private Limited

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