



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

Licence no.: MFG/IVD/2021/000071

Date: 01/08/2024

Document ID: COA/TN/007HBd/20T

|                   |                                                     |
|-------------------|-----------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> HBV                            |
| Generic Name      | Chip-based Real Time PCR Test for Hepatitis B Virus |
| Lot No.           | 007HB                                               |
| Set No.           | d                                                   |
| Mfg. Date         | 2024-03                                             |
| Exp. Date         | 2026-02                                             |
| Pack Size         | 20T                                                 |
| 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    |              |
|                                        | HBV          | Control      |
| Non Template Control                   | ND           | ND           |
| Negative Sample                        | ND           | 28.40 ± 0.64 |
| Positive sample 1                      | 23.27 ± 0.47 | 28.37 ± 0.51 |
| Positive sample 2                      | 30.29 ± 1.13 | 25.32 ± 0.49 |
| Positive Sample 3                      | 27.64 ± 0.30 | 27.83 ± 0.30 |
| 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  
Department: Quality Control  
Designation: QC Head

FM/QT/219-01

**Molbio Diagnostics Private Limited**

Page 1 of 1

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