



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

Licence no.: MFG/IVD/2019/000018

Date: 09/12/2023

Document ID: COA/TN/GB011c

|                   |                                                                |
|-------------------|----------------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> GBS                                       |
| Generic Name      | Chip-based Real Time PCR Test for <i>Group B Streptococcus</i> |
| Lot No.           | GB011                                                          |
| Set No.           | c                                                              |
| Mfg. Date         | 2022-09                                                        |
| Exp. Date         | 2024-08                                                        |
| Pack Size         | 5T, 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    |              |
|                                        | Dengue       | Control      |
| Non Template Control                   | ND           | ND           |
| Negative Sample                        | ND           | 27.46 ± 0.12 |
| Positive sample 1                      | 23.72 ± 0.19 | 27.35 ± 0.12 |
| Positive sample 2                      | 25.86 ± 0.17 | 27.10 ± 0.28 |
| Positive Sample 3                      | 30.87 ± 0.59 | 26.48 ± 0.75 |
| 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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