



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

Licence No.: MFG/IVD/2019/000018

Date: 14/11/2024

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|                   |                                                                |
|-------------------|----------------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> CDI                                       |
| Generic Name      | Chip-based Real Time PCR Test for <i>Clostridium difficile</i> |
| Lot No.           | CS005                                                          |
| Set No.           | a                                                              |
| Mfg. Date         | 2024-10                                                        |
| Exp. Date         | 2026-09                                                        |
| Pack Size         | 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    |              |
|                          | Clostridium  | Control      |
| Non Template Control     | ND           | ND           |
| Negative Sample          | ND           | 28.97 ± 0.68 |
| Positive sample 1        | 22.19 ± 0.35 | 27.82 ± 0.56 |
| Positive sample 2        | 23.53 ± 0.36 | 28.60 ± 0.61 |
| Positive Sample 3        | 30.82 ± 0.68 | 25.52 ± 0.21 |

\*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.



**Name : Dr. Praveen Kumar**  
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**Designation: QC Head**

## **Molbio Diagnostics Pvt. Ltd.**

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