



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

Licence no.: MFG/IVD/2019/000018

Date: 20/07/2024

Document ID:COA/TN/DC033a/20T

|                   |                                                                 |
|-------------------|-----------------------------------------------------------------|
| Product Name      | Truenat® Dengue/Chikungunya                                     |
| Generic Name      | Chip-based Real Time Duplex PCR Test for Dengue and Chikungunya |
| Lot No.           | DC033                                                           |
| Set No.           | a                                                               |
| Mfg. Date         | 2024-07                                                         |
| Exp. Date         | 2026-06                                                         |
| 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    |              |              |
|----------------------|--------------|--------------|--------------|
|                      | Dengue       | Chikungunya  | Control      |
| Non Template Control | ND           | ND           | ND           |
| Negative Sample      | ND           | ND           | 26.69 ± 0.49 |
| Positive Sample 1    | 26.93 ± 0.34 | ND           | 27.76 ± 0.44 |
| Positive Sample 2    | ND           | 28.40 ± 0.22 | 28.05 ± 0.89 |
| Positive Sample 3    | 29.08 ± 0.69 | 30.18 ± 1.00 | 26.20 ± 0.26 |

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.**



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