



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

Licence no.: MFG/IVD/2021/000071

Date: 08/05/2024

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|                   |   |
|-------------------|---|
| Product Name      | Truenat <sup>®</sup> MTB  |
| Generic Name      | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No.           | 085TB   |
| Set No.           | h   |
| Mfg. Date         | 2024-05   |
| Exp. Date         | 2026-04   |
| Pack Size         | 5T  |
| 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    |              |
|                          | MTB          | Control      |
| Non Template Control     | ND           | ND           |
| Negative Sample          | ND           | 28.20 ± 0.42 |
| Positive sample 1        | 26.89 ± 0.50 | 29.08 ± 0.59 |
| Positive sample 2        | 31.39 ± 1.10 | 26.04 ± 0.22 |
| Positive Sample 3        | 24.21 ± 0.34 | 29.06 ± 0.29 |

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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