



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

Licence no.: MFG/IVD/2019/000018

Date: 24/07/2023

Document ID: COA/TN/TB248c

|                   |   |
|-------------------|---|
| Product Name      | Truenat <sup>®</sup> MTB  |
| Generic Name      | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No.           | TB248   |
| Set No.           | c   |
| Mfg. Date         | 2023-07   |
| Exp. Date         | 2025-06   |
| Pack Size         | 5T, 50T   |
| 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           | 27.79 ± 0.49 |
| Positive sample 1                      | 21.25 ± 0.64 | 28.47 ± 0.56 |
| Positive sample 2                      | 24.84 ± 0.39 | 27.26 ± 0.16 |
| Positive Sample 3                      | 29.46 ± 0.63 | 24.44 ± 0.20 |
| 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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## Molbio Diagnostics Private Limited

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