

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

Licence No.: MFG/IVD/2019/000018

Date: 06/12/2024

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|                   |   |
|-------------------|---|
| Product Name      | Truenat <sup>®</sup> MTB Plus                                       |
| Generic Name      | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No.           | TP062   |
| Set No.           | a   |
| Mfg. Date         | 2024-11   |
| Exp. Date         | 2026-10   |
| 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 PLUS     | Control      |
| Non Template Control     | ND           | ND           |
| Negative Sample          | ND           | 28.50 ± 0.39 |
| Positive sample 1        | 21.79 ± 0.54 | 24.23 ± 0.14 |
| Positive sample 2        | 24.69 ± 0.37 | 26.49 ± 0.51 |
| Positive Sample 3        | 29.43 ± 0.58 | 25.67 ± 0.48 |

ND – Not detected, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry

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

  
**Name : Dr. Praveen Kumar**  
**Department: Quality Control**  
**Designation: QC Head**

