

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

Licence No.: MFG/IVD/2021/000071

Date: 13/03/2025

Document ID:COA/TN/359TB/50T

| | |
|-------------------|---|
| Product Name | Truenat [®] MTB |
| Generic Name | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No. | 359TB |
| Set No. | NA |
| Mfg. Date | 2025-03 |
| Exp. Date | 2027-02 |
| Pack Size | 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 | Pouch 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 | 25.97 ± 0.29 |
| Positive sample 1 | 30.77 ± 0.82 | 25.23 ± 0.20 |
| Positive sample 2 | 27.37 ± 0.32 | 26.95 ± 0.11 |
| Positive Sample 3 | 24.00 ± 0.56 | 27.80 ± 0.19 |

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

