



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

Licence no.: MFG/IVD/2021/000071

Date:

DocumentID: COA/TN/008TPI/25T

| | |
|-------------------|---|
| Product Name | Truenat [®] MTB Plus |
| Generic Name | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No. | 008TP |
| Set No. | I |
| Mfg. Date | 2024-02 |
| Exp. Date | 2026-01 |
| Pack Size | 25T |
| 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 | 29.19 ± 0.42 |
| Positive sample 1 | 29.98 ± 0.87 | 25.19 ± 0.24 |
| Positive sample 2 | 25.57 ± 0.31 | 27.80 ± 0.23 |
| Positive Sample 3 | 23.53 ± 0.14 | 28.69 ± 0.37 |

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
Department: Quality Control
Designation: QC Head

FM/QT/219-01

Page 1 of 1

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO