



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

Licence no.: MFG/IVD/2021/000071

Date: 22/07/2024

DocumentID:COA/TN/015TPa/20T

|                   |                                                                     |
|-------------------|---------------------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> MTB Plus                                       |
| Generic Name      | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No.           | 015TP                                                               |
| Set No.           | a                                                                   |
| Mfg. Date         | 2024-07                                                             |
| Exp. Date         | 2026-06                                                             |
| Pack Size         | 20T                                                                 |
| 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           | 28.29 ± 0.69 |
| Positive sample 1        | 29.93 ± 0.44 | 25.64 ± 0.59 |
| Positive sample 2        | 23.93 ± 0.19 | 28.18 ± 0.12 |
| Positive Sample 3        | 28.09 ± 0.28 | 28.23 ± 0.12 |

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

Page 1 of 1

FM/QT/219-01

## 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