

Molbio Diagnostics Limited

(Formerly Molbio Diagnostics Private Limited) L-46, Phase II D, Verna Industrial Estate Verna, Goa-403722, India 3+918326724888 www.molbiodiagnostics.com

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

Licence No.: MFG/IVD/2019/000018

Date: 10/09/2025

| Document | ID:COA/TN/TP090 | |
|----------|-----------------|---|
| | | - |

| Truenat® MTB Plus |
|--|
| Chip-based Real Time PCR Test for Mycobacterium tuberculosis |
| TP090 |
| NA |
| 2025-05 |
| 2027-04 |
| 5T, 50T |
| 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 | | | | | |
|--|--------------|--------------|--|--|--|
| | Ct Values | | | | |
| Samples | MTB PLUS | Control | | | |
| Non Template Control | ND | ND | | | |
| Negative Sample | ND | 26.68 ± 0.39 | | | |
| Positive sample 1 | 23.53 ± 0.48 | 25.98 ± 0.21 | | | |
| Positive sample 2 | 27.42 ± 0.70 | 28.00 ± 0.87 | | | |
| Positive Sample 3 | 30.41 ± 1.15 | 26.13 ± 0.54 | | | |
| 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 MK **Department: Quality Control Designation: QC Head**