

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

Licence No.: MFG/IVD/2019/000018

Date: 26/03/2026

Document ID: COA/TN/I0035TP

| | |
|--------------------------|---|
| Product Name | Truenat [®] MTB Plus |
| Generic Name | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No. | I0035TP |
| Set No. | NA |
| Mfg. Date | 2026-03 |
| Exp. Date | 2028-02 |
| 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 | 27.29 ± 0.57 |
| Positive Sample 1 | 23.44 ± 0.19 | 27.40 ± 0.54 |
| Positive Sample 2 | 26.17 ± 0.55 | 28.89 ± 0.30 |
| Positive Sample 3 | 28.51 ± 0.94 | 28.54 ± 0.97 |

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

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



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