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**Molbio Diagnostics Limited**
(Formerly Molbio Diagnostics Private Limited)
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# MOLBIO DIAGNOSTICS LIMITED
## EN ISO 13485:2016 certified company
## CERTIFICATE OF ANALYSIS

**Licence No.: MFG/IVD/2021/000071**

**Date: 26/10/2026**
**Document ID: COA/TN/V0543TB**

| | |
|---|---|
| **Product Name** | **Truenat® MTB** |
| **Generic Name** | **Chip-based Real Time PCR Test for *Mycobacterium tuberculosis*** |
| **Lot No.** | **V0543TB** |
| **Set No.** | **NA** |
| **Mfg. Date** | **2026-10** |
| **Exp. Date** | **2028-09** |
| **Pack Size** | **5T, 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 DNase and RNase free filter barrier microtip | 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 | 26.95 ± 0.37 |
| **Positive sample 1** | 24.54 ± 0.16 | 27.96 ± 0.17 |
| **Positive sample 2** | 27.74 ± 0.28 | 27.74 ± 0.35 |
| **Positive Sample 3** | 31.67 ± 0.67 | 26.36 ± 0.23 |
| ND – Not detected, Ct- Cycle threshold | | |

Mfg- Manufacturing, Exp- Expiry

**The lot is tested and verified as per QC standards and is approved.**

MOLBIO DIAGNOSTICS LIMITED GOA

**Name: Dr. Praveen Kumar M**
**Department: Quality Control**
**Designation: QC Head**



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