

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

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

**Date:** 26/11/2025

**Document ID:** COA/TN/875TB

|                          |                                                                     |
|--------------------------|---------------------------------------------------------------------|
| <b>Product Name</b>      | Truenat <sup>®</sup> MTB                                            |
| <b>Generic Name</b>      | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| <b>Lot No.</b>           | 875TB                                                               |
| <b>Set No.</b>           | NA                                                                  |
| <b>Mfg. Date</b>         | 2025-11                                                             |
| <b>Exp. Date</b>         | 2027-10                                                             |
| <b>Pack Size</b>         | 5T, 50T                                                             |
| <b>Storage condition</b> | 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 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          | Control      |
| Non Template Control     | ND           | ND           |
| Negative Sample          | ND           | 28.65 ± 0.21 |
| Positive sample 1        | 31.34 ± 1.00 | 27.39 ± 0.54 |
| Positive sample 2        | 27.26 ± 0.23 | 27.10 ± 0.27 |
| Positive Sample 3        | 23.08 ± 0.32 | 26.27 ± 0.35 |

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  
**Department:** Quality Control  
**Designation:** QC Head

