

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

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

**Date: 08/04/2025**

**Document ID: COA/TN/403TB/50T**

|                          |                                                                            |
|--------------------------|----------------------------------------------------------------------------|
| <b>Product Name</b>      | <b>Truenat<sup>®</sup> MTB</b>                                             |
| <b>Generic Name</b>      | <b>Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i></b> |
| <b>Lot No.</b>           | <b>403TB</b>                                                               |
| <b>Set No.</b>           | <b>NA</b>                                                                  |
| <b>Mfg. Date</b>         | <b>2025-04</b>                                                             |
| <b>Exp. Date</b>         | <b>2027-03</b>                                                             |
| <b>Pack Size</b>         | <b>50T</b>                                                                 |
| <b>Storage condition</b> | <b>2°C to 30°C</b>                                                         |

**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

| <b>Sr. No.</b> | <b>Components in each kit</b>                                                    | <b>Specification</b>                   | <b>Observation</b>      |
|----------------|----------------------------------------------------------------------------------|----------------------------------------|-------------------------|
| 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                    |

| <b>Performance testing data</b> |                  |                |
|---------------------------------|------------------|----------------|
| <b>Samples</b>                  | <b>Ct Values</b> |                |
|                                 | <b>MTB</b>       | <b>Control</b> |
| <b>Non Template Control</b>     | ND               | ND             |
| <b>Negative Sample</b>          | ND               | 27.01 ± 0.25   |
| <b>Positive sample 1</b>        | 31.42 ± 0.25     | 25.60 ± 0.29   |
| <b>Positive sample 2</b>        | 24.13 ± 0.30     | 27.99 ± 0.42   |
| <b>Positive Sample 3</b>        | 27.12 ± 0.59     | 26.89 ± 0.22   |

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**

