

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

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

**Date: 29/12/2025**

**Document ID:COA/TN/920TB**

|                          |   |
|--------------------------|---|
| <b>Product Name</b>      | Truenat® MTB  |
| <b>Generic Name</b>      | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| <b>Lot No.</b>           | 920TB   |
| <b>Set No.</b>           | NA  |
| <b>Mfg. Date</b>         | 2025-12   |
| <b>Exp. Date</b>         | 2027-11   |
| <b>Pack Size</b>         | 5T, 50T   |
| <b>Storage condition</b> | 2°C to 30°C   |

**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               | 27.07 ± 0.37   |
| <b>Positive sample 1</b>        | 31.36 ± 0.04     | 27.17 ± 0.23   |
| <b>Positive sample 2</b>        | 23.69 ± 0.34     | 26.98 ± 0.17   |
| <b>Positive Sample 3</b>        | 27.38 ± 0.13     | 26.50 ± 0.00   |

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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