



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

Licence no.: MFG/IVD/2021/000071

Date: 24/08/2024

Document ID:COA/TN/103TBh/5T

|                   |                                                                     |
|-------------------|---------------------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> MTB                                            |
| Generic Name      | Chip-based Real Time PCR Test for <i>Mycobacterium tuberculosis</i> |
| Lot No.           | 103TB                                                               |
| Set No.           | h                                                                   |
| Mfg. Date         | 2024-08                                                             |
| Exp. Date         | 2026-07                                                             |
| Pack Size         | 5T                                                                  |
| 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          | Control      |
| Non Template Control                   | ND           | ND           |
| Negative Sample                        | ND           | 27.89 ± 0.78 |
| Positive sample 1                      | 30.85 ± 0.81 | 26.08 ± 0.76 |
| Positive sample 2                      | 27.83 ± 0.33 | 28.80 ± 0.27 |
| Positive Sample 3                      | 23.24 ± 0.51 | 27.76 ± 0.48 |
| 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  
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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO