

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

Licence No.: MFG/IVD/2021/000071

Date: 25/12/2025

Document ID: COA/TN/227TX

|                   |  |
|-------------------|--|
| Product Name      | Truenat <sup>®</sup> MTB-RIF Dx  |
| Generic Name      | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> |
| Lot No.           | 227TX  |
| Set No.           | NA   |
| Mfg. Date         | 2025-11  |
| Exp. Date         | 2027-10  |
| Pack Size         | 5T, 20T  |
| 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 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    |              |              | Results                     |
|  | Tm           |              | Control      |                             |
|  | P2           | P1           |              |                             |
| Positive sample 1                            | 66.42 ± 0.36 | 66.90± 0.25  | 70.81 ± 0.40 | RIF Resistance detected     |
| Positive sample 2                            | 72.36 ± 0.38 | 66.73 ± 0.63 | 70.81 ± 0.49 | RIF Resistance not detected |
| Positive sample 3                            | 72.37 ± 0.48 | 66.64 ± 0.48 | 70.24 ± 0.65 | RIF Resistance not detected |
| Tm- Melting temperature, Ct- Cycle threshold |              |              |              |                             |

Tm- Melting temperature, 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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Designation: QC Head



FM/QT/219-03

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