

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

Licence No.: MFG/IVD/2021/000071

Date: 21/11/2025

Document ID: COA/TN/203TX

| | |
|-------------------|--|
| Product Name | Truenat [®] MTB-RIF Dx |
| Generic Name | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> |
| Lot No. | 203TX |
| Set No. | NA |
| Mfg. Date | 2025-09 |
| Exp. Date | 2027-08 |
| 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 | 66.82 ± 0.22 | 66.55 ± 0.30 | 70.55 ± 0.50 | RIF Resistance detected |
| Positive sample 2 | 72.66 ± 0.35 | 66.40 ± 0.34 | 70.78 ± 0.56 | RIF Resistance not detected |
| Positive sample 3 | 72.61 ± 0.31 | 66.92 ± 0.45 | 70.44 ± 0.38 | 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
Department: Quality Control
Designation: QC Head

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