

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

Licence No.: MFG/IVD/2021/000071

Date: 20/02/2025

Document ID: COA/TN/072TX/20T

| | |
|-------------------|--|
| Product Name | Truenat [®] MTB-RIF Dx |
| Generic Name | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> |
| Lot No. | 072TX |
| Set No. | NA |
| Mfg. Date | 2025-02 |
| Exp. Date | 2027-01 |
| Pack Size | 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 | 65.44 ± 0.39 | 66.22 ± 0.34 | 71.09 ± 0.38 | RIF Resistance detected |
| Positive sample 2 | 72.19 ± 0.36 | 66.41 ± 0.28 | 71.05 ± 0.42 | RIF Resistance not detected |
| Positive sample 3 | 71.97 ± 0.34 | 66.34 ± 0.19 | 71.04 ± 0.45 | 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

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Designation: QC Head



FM/QT/219-03

Page 1 of 1