

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

Licence No.: MFG/IVD/2019/000018

Date: 22/01/2026

Document ID: COA/TN/TX126

| | |
|-------------------|--|
| Product Name | Truenat [®] MTB-RIF Dx |
| Generic Name | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> |
| Lot No. | TX126 |
| Set No. | NA |
| Mfg. Date | 2025-11 |
| Exp. Date | 2027-10 |
| Pack Size | 5T, 20T |
| Storage condition | 2°C to 30°C |

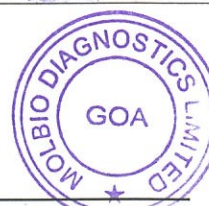
PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

| Sr. No. | Components in each kit | Specification | Observation |
|---------|--|--|-------------------------|
| 01 | Number of pouches as per pack size | Should be present | Present |
| 02 | 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 | | | Results |
| | Tm | | Control | |
| | P2 | P1 | | |
| Positive sample 1 | 66.18 ± 0.32 | 66.36 ± 0.42 | 70.61 ± 0.55 | RIF Resistance detected |
| Positive sample 2 | 71.95 ± 0.40 | 66.38 ± 0.49 | 70.10 ± 0.55 | RIF Resistance not detected |
| Positive sample 3 | 72.05 ± 0.43 | 66.69 ± 0.44 | 70.26 ± 0.57 | RIF Resistance not detected |
| Tm- Melting temperature, Ct- Cycle threshold | | | | |

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.



for Name : Dr. Praveen Kumar MK
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Designation: QC Head