



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

Licence no.: MFG/IVD/2021/000071

Date: 31/07/2024

Document ID: COA/TN/030TXb/20T

|                   |                                                                                          |
|-------------------|------------------------------------------------------------------------------------------|
| Product Name      | Truenat® MTB-RIF Dx                                                                      |
| Generic Name      | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> |
| Lot No.           | 030TX                                                                                    |
| Set No.           | b                                                                                        |
| Mfg. Date         | 2024-07                                                                                  |
| Exp. Date         | 2026-06                                                                                  |
| 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      | 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                            | 65.49 ± 0.30 | 66.55 ± 0.18 | 70.69 ± 0.53 | RIF Resistance detected     |
| Positive sample 2                            | 72.07 ± 0.26 | 66.75 ± 0.28 | 70.49 ± 0.63 | RIF Resistance not detected |
| Positive sample 3                            | 72.39 ± 0.15 | 66.66 ± 0.20 | 70.39 ± 0.31 | RIF Resistance not detected |
| Tm- Melting temperature, Ct- Cycle threshold |              |              |              |                             |

Tm- Melting temperature, Ct- Cycle threshold

\*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices, RIF-Rifampicin

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.

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