



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

Licence no.: MFG/IVD/2021/000071

Date: 26/10/2023

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|                   |                                                                                          |
|-------------------|------------------------------------------------------------------------------------------|
| Product Name      | Truenat® MTB-RIF Dx                                                                      |
| Generic Name      | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> |
| Lot No.           | 014TX                                                                                    |
| Set No.           | d                                                                                        |
| Mfg. Date         | 2023-10                                                                                  |
| Exp. Date         | 2025-09                                                                                  |
| 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                           | 66.56 ± 0.51 | 66.61 ± 0.41 | 70.72 ± 0.64 | RIF Resistance detected     |
| Positive sample 2                           | 72.42 ± 0.53 | 66.58 ± 0.48 | 70.39 ± 0.43 | RIF Resistance not detected |
| Positive sample 3                           | 72.06 ± 0.65 | 66.42 ± 0.56 | 71.01 ± 0.68 | RIF Resistance not detected |
| Tm- Melting temprature, Ct- Cycle threshold |              |              |              |                             |

\*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices, RIF-Rifampicin  
Manufacturing records are verified, checked and product is manufactured as per GMP,  
GMP, samples tested and lot is QC approved for sale purpose.

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**Molbio Diagnostics Private Limited**