

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

Licence No.: MFG/IVD/2021/000071

Date: 23/01/2025

Document ID: COA/TN/054TX/5T

|                   |                                                                                          |
|-------------------|------------------------------------------------------------------------------------------|
| Product Name      | Truenat <sup>®</sup> MTB-RIF Dx                                                          |
| Generic Name      | Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i> |
| Lot No.           | 054TX                                                                                    |
| Set No.           | NA                                                                                       |
| Mfg. Date         | 2025-01                                                                                  |
| Exp. Date         | 2026-12                                                                                  |
| Pack Size         | 5T                                                                                       |
| 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                    |

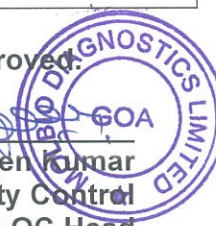
| Performance testing data                     |              |              |              |                             |
|----------------------------------------------|--------------|--------------|--------------|-----------------------------|
| Samples                                      | Ct Values    |              |              | Results                     |
|                                              | Tm           |              | Control      |                             |
|                                              | P2           | P1           |              |                             |
| Positive sample 1                            | 65.60 ± 0.39 | 66.30± 0.50  | 70.31 ± 0.73 | RIF Resistance detected     |
| Positive sample 2                            | 71.58 ± 0.38 | 66.19 ± 0.37 | 70.18 ± 0.29 | RIF Resistance not detected |
| Positive sample 3                            | 72.16 ± 0.26 | 66.26 ± 0.28 | 70.67 ± 0.26 | 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



FM/QT/219-03

Page 1 of 1