

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

Licence No.: MFG/IVD/2019/000018

Date: 14/01/2025  
Document ID: COA/TN/TX095g/20T

|                   |                                                                                          |
|-------------------|------------------------------------------------------------------------------------------|
| 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.           | TX095                                                                                    |
| Set No.           | g                                                                                        |
| Mfg. Date         | 2024-03                                                                                  |
| Exp. Date         | 2026-02                                                                                  |
| 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                           | 66.02 ± 0.45 | 66.61 ± 0.32 | 69.57 ± 0.50 | RIF Resistance detected     |
| Positive sample 2                           | 72.16 ± 0.29 | 66.73 ± 0.27 | 69.78 ± 0.64 | RIF Resistance not detected |
| Positive sample 3                           | 72.24 ± 0.48 | 66.80 ± 0.32 | 69.65 ± 0.44 | RIF Resistance not detected |
| Tm- Melting temprature, Ct- Cycle threshold |              |              |              |                             |

Tm- Melting temprature, 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

*for*

