

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

Licence No.: MFG/IVD/2021/000071

Date: 27/02/2026

Document ID: COA/TN/V0012TX

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.	V0012TX
Set No.	NA
Mfg. Date	2026-02
Exp. Date	2028-01
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	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	67.88 ± 0.75	67.03 ± 0.20	70.06 ± 0.25	RIF Resistance detected
Positive sample 2	72.78 ± 0.18	66.85 ± 0.22	70.19 ± 0.25	RIF Resistance not detected
Positive sample 3	72.60 ± 0.39	66.85 ± 0.23	70.25 ± 0.49	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

Name : Dr. Praveen Kumar  
Department: Quality Control  
Designation: QC Head

