

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

Licence No.: MFG/IVD/2021/000071

Date: 15/05/2026

Document ID: COA/TN/V0047TX

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.	V0047TX
Set No.	NA
Mfg. Date	2026-04
Exp. Date	2028-03
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 DNase and RNase free filter barrier microtip	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	Tm values		Control	Results
	P2	P1		
Positive sample 1	66.66 ± 0.29	66.80 ± 0.26	69.77 ± 0.22	RIF Resistance detected
Positive sample 2	72.35 ± 0.20	67.17 ± 0.31	70.40 ± 0.39	RIF Resistance not detected
Positive sample 3	72.51 ± 0.44	66.86 ± 0.40	70.04 ± 0.35	RIF Resistance not detected

Tm- Melting temperature

Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC standards and is approved.

  
Name : Dr. Praveen Kumar  
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Designation: QC Head

