

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

Licence No.: MFG/IVD/2021/000071

Date: 27/04/2026

Document ID: COA/TN/V0034TX

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.	V0034TX
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	66.68 ± 0.34	66.72 ± 0.37	70.41 ± 0.41	RIF Resistance detected
Positive sample 2	72.50 ± 0.13	66.88 ± 0.22	70.53 ± 0.22	RIF Resistance not detected
Positive sample 3	72.75 ± 0.16	66.95 ± 0.11	70.28 ± 0.12	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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