

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

License No.: MFG/IVD/2021/000071

Date: 05/02/2026

Document ID: COA/TN/273TX

Product Name	Truenat® MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	273TX
Set No.	NA
Mfg. Date	2025-11
Exp. Date	2027-10
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	66.31 ± 0.27	66.73 ± 0.13	70.20 ± 0.35	RIF Resistance detected	
Positive sample 2	72.79 ± 0.36	66.63 ± 0.24	70.38 ± 0.30	RIF Resistance not detected	
Positive sample 3	72.81 ± 0.26	66.95 ± 0.27	70.32 ± 0.45	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

