

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

Licence No.: MFG/IVD/2021/000071

Date: 30/01/2026

Document ID: COA/TN/256TX

Product Name	Truenat® MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	256TX
Set No.	NA
Mfg. Date	2025-12
Exp. Date	2027-11
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	67.05 ± 0.24	66.68 ± 0.24	70.39 ± 0.24	70.39 ± 0.24	RIF Resistance detected		
Positive sample 2	72.49 ± 0.36	67.01 ± 0.22	70.49 ± 0.19	70.49 ± 0.19	RIF Resistance not detected		
Positive sample 3	72.61 ± 0.27	67.07 ± 0.65	70.87 ± 0.31	70.87 ± 0.31	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

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