

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

Licence No.: MFG/IVD/2021/000071

Date: 31/01/2026

Document ID: COA/TN/260TX

Product Name	Truenat® MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	260TX
Set No.	NA
Mfg. Date	2026-01
Exp. Date	2027-12
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	66.97 ± 0.29	66.74 ± 0.24	70.14 ± 0.27	70.14 ± 0.27	RIF Resistance detected		
Positive sample 2	72.78 ± 0.21	66.70 ± 0.13	69.90 ± 0.53	69.90 ± 0.53	RIF Resistance not detected		
Positive sample 3	72.82 ± 0.36	66.80 ± 0.28	70.22 ± 0.35	70.22 ± 0.35	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

