

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

Licence No.: MFG/IVD/2021/000071

Date: 21/11/2025

Document ID: COA/TN/202TX

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.	202TX
Set No.	NA
Mfg. Date	2025-09
Exp. Date	2027-08
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	66.86 ± 0.41	66.45 ± 0.31	70.44 ± 0.51	RIF Resistance detected
Positive sample 2	72.42 ± 0.58	66.53 ± 0.49	70.90 ± 0.44	RIF Resistance not detected
Positive sample 3	72.61 ± 0.28	67.13 ± 0.20	70.69 ± 0.17	RIF Resistance not detected
Tm- Melting temperature, Ct- Cycle threshold				

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



FM/QT/219-03

Page 1 of 1