

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

Licence No.: MFG/IVD/2021/000071

Date: 24/12/2025

Document ID: COA/TN/224TX

Product Name	Truenat® MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	224TX
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.**

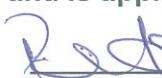
Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouch Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data							
Samples	Ct Values			Control	Results		
	Tm		P1				
	P2	P1					
Positive sample 1	66.76 ± 0.27	66.85 ± 0.36	70.25 ± 0.32	70.25 ± 0.32	RIF Resistance detected		
Positive sample 2	72.34 ± 0.23	66.62 ± 0.14	70.48 ± 0.54	70.48 ± 0.54	RIF Resistance not detected		
Positive sample 3	72.60 ± 0.36	67.33 ± 0.33	69.92 ± 0.36	69.92 ± 0.36	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

FM/QT/219-03

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