

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

Licence No.: MFG/IVD/2021/000071

Date: 25/12/2025

Document ID: COA/TN/225TX

Product Name	Truenat® MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	225TX
Set No.	NA
Mfg. Date	2025-10
Exp. Date	2027-09
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	66.71 ± 0.30	66.91 ± 0.43	70.33 ± 0.69	RIF Resistance detected	
Positive sample 2	72.35 ± 0.32	66.88 ± 0.38	70.14 ± 0.71	RIF Resistance not detected	
Positive sample 3	72.63 ± 0.34	67.09 ± 0.52	69.78 ± 0.53	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

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