

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

Licence No.: MFG/IVD/2021/000071

Date: 23/12/2025

Document ID: COA/TN/222TX

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.	222TX
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			Results
	Tm		Control	
	P2	P1		
Positive sample 1	66.75 ± 0.20	66.49 ± 0.14	69.92 ± 0.49	RIF Resistance detected
Positive sample 2	71.99 ± 0.27	66.23 ± 0.27	70.54 ± 0.43	RIF Resistance not detected
Positive sample 3	72.27 ± 0.17	66.61 ± 0.26	69.96 ± 0.23	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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Designation: QC Head

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