

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

Licence No.: MFG/IVD/2021/000071

Date: 04/07/2025

Document ID: COA/TN/114TX/25T

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.	114TX
Set No.	NA
Mfg. Date	2025-06
Exp. Date	2027-05
Pack Size	25T
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	65.50 ± 0.48	66.56 ± 0.41	71.11 ± 0.49	RIF Resistance detected
Positive sample 2	71.99 ± 0.42	66.26 ± 0.43	70.66 ± 0.41	RIF Resistance not detected
Positive sample 3	72.16 ± 0.47	66.49 ± 0.32	70.71 ± 0.56	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**



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