

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

Licence No.: MFG/IVD/2021/000071

Date: 18/07/2025

Document ID: COA/TN/138TX/20T

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.	138TX
Set No.	NA
Mfg. Date	2025-06
Exp. Date	2027-05
Pack Size	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	65.86 ± 0.34	66.59 ± 0.33	70.09 ± 0.40	RIF Resistance detected
Positive sample 2	72.14 ± 0.36	66.95 ± 0.23	70.47 ± 0.64	RIF Resistance not detected
Positive sample 3	71.99 ± 0.37	66.90 ± 0.42	70.56 ± 0.90	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  
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Designation: QC Head



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