

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

Licence No.: MFG/IVD/2021/000071

Date: 14/05/2026

Document ID: COA/TN/V0045TX

Product Name	Truenat [®] MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	V0045TX
Set No.	NA
Mfg. Date	2026-04
Exp. Date	2028-03
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 DNase and RNase free filter barrier microtip	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	Tm values		Control	Results
	P2	P1		
Positive sample 1	66.69 ± 0.45	66.61 ± 0.28	69.93 ± 0.72	RIF Resistance detected
Positive sample 2	72.79 ± 0.18	66.79 ± 0.26	69.85 ± 0.28	RIF Resistance not detected
Positive sample 3	72.46 ± 0.18	66.51 ± 0.22	70.12 ± 0.27	RIF Resistance not detected

Tm- Melting temperature

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

