

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

Licence No.: MFG/IVD/2019/000018

Date: 03/02/2026

Document ID:COA/TN/TX129

Product Name	Truenat [®] MTB-RIF Dx
Generic Name	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
Lot No.	TX129
Set No.	NA
Mfg. Date	2026-01
Exp. Date	2027-12
Pack Size	5T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification		Observation
		Should be present	Present	
01	Number of pouches as per pack size	Should be present	Present	
02	Pouches 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	66.89 ± 0.25	66.82 ± 0.22	70.24 ± 0.61	RIF Resistance detected	
Positive sample 2	72.65 ± 0.35	67.06 ± 0.40	70.13 ± 0.27	RIF Resistance not detected	
Positive sample 3	72.13 ± 0.47	66.73 ± 0.40	70.59 ± 0.31	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 MK
 Department: Quality Control
 Designation: QC Head