



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2021/000071

Date:10/05/2022

Doc ID: COA/TN/004TX

BRAND NAME	Truenat <sup>®</sup> MTB-RIF Dx		
GENERIC NAME	Chip-based Real Time Duplex PCR Test for Rifampicin resistant <i>Mycobacterium tuberculosis</i>		
LOT No.	004TX		
MFG. DATE	2022-05		
EXP. DATE	2024-04		
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.: B-004-TX


PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 25 no 50 no.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE				
Specificity Tests	Tm		Control	Result
	P2	P1		
Sample 1	66.56	66.36	70.82	RIF RESISTANCE DETECTED
	66.33	66.33	70.66	RIF RESISTANCE DETECTED
Sample 2	71.55	65.96	70.75	RIF RESISTANCE NOT DETECTED
	72.61	67.28	69.55	RIF RESISTANCE NOT DETECTED
	72.22	66.31	70.54	RIF RESISTANCE NOT DETECTED

\*Tm-Melting temperature, RIF-Rifampicin

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS QC APPROVED FOR TESTING PURPOSE

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head  
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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO