



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:09/05/2022

Doc ID: COA/TN/003TX

BRAND NAME	Truenat <sup>®</sup> MTB-RIF Dx
GENERIC NAME	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
LOT No.	003TX
MFG. DATE	2022-05
EXP. DATE	2024-04
PACK SIZE	5T, 20T, 25T, 50T
STORAGE	2°C to 30°C

A.R. No.: B-003-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	66.7	66.49	70.38	RIF RESISTANCE DETECTED
	67.42	66.94	70.17	RIF RESISTANCE DETECTED
Sample 2	71.33	66.4	69.99	RIF RESISTANCE NOT DETECTED
	71.76	66.48	70.19	RIF RESISTANCE NOT DETECTED
	72.03	67.02	69.41	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 SALE.

QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0