



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

Mfg. Lic. No. : MFG/IVD/2019/000018

Date: 21/01/2021

BRAND NAME	Truenat™ MTB-RIF Dx
GENERIC NAME	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>
LOT No.	TX057
MFG. DATE	2021-01
EXP. DATE	2022-12
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-TX-057	

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.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE				
Specificity Tests	Tm		Control	Result
	P1	P2		
Sample 1	66.2	65.34	70.7	RIF RESISTANCE DETECTED
	67.07	65.87	70.45	RIF RESISTANCE DETECTED
	65.96	65.29	70.94	RIF RESISTANCE DETECTED
	66.04	65.09	71.21	RIF RESISTANCE DETECTED
Sample 2	67.03	73.05	70.33	RIF RESISTANCE NOT DETECTED
	66.63	72.05	70.66	RIF RESISTANCE NOT DETECTED
	67.38	72.96	70.01	RIF RESISTANCE NOT DETECTED
	66.43	72.13	70.84	RIF RESISTANCE NOT DETECTED
	66.43	72.13	70.84	RIF RESISTANCE NOT DETECTED
	66.89	72.29	70.47	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 RELEASED FOR SALE

QUALITY CONTROL
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Designation: QC Head
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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0