



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

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

Date: 12/04/2021

Doc ID: COA/TN/TX063

BRAND NAME	Truenat™ MTB-RIF Dx		
GENERIC NAME	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>		
LOT No.	TX063		
MFG. DATE	2021-03		
EXP. DATE	2023-02		
PACK SIZE	5T, 20T, 50T		
STORAGE	2°C to 30°C		A.R. No. : B-TX-063

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, 50 no.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE				
Specificity Tests	Tm		Control	Result
	P1	P2		
Sample 1	66.52	66.71	71.49	RIF RESISTANCE DETECTED
	66.61	66.42	71.54	RIF RESISTANCE DETECTED
	66.47	66.64	72	RIF RESISTANCE DETECTED
	65.47	65.47	72.26	RIF RESISTANCE DETECTED
Sample 2	67.14	72.17	72.4	RIF RESISTANCE NOT DETECTED
	66.75	71.87	72.6	RIF RESISTANCE NOT DETECTED
	66.82	72.03	72.77	RIF RESISTANCE NOT DETECTED
	66.43	71.71	72.97	RIF RESISTANCE NOT DETECTED
	65.73	71.19	74.46	RIF RESISTANCE NOT DETECTED
	66.95	72.3	72.91	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

Praveen
QUALITY CONTROL
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for Designation: QC Head
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