



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

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

Date: 02/10/2020

BRAND NAME	Truenat™ MTB-RIF Dx		
GENERIC NAME	Chip-based Real Time PCR Test for Rifampicin resistant <i>Mycobacterium tuberculosis</i>		
LOT No.	TX042		
MFG. DATE	2020-08		
EXP. DATE	2022-07		
PACK SIZE	5T, 20T		
STORAGE	2°C to 30°C		A.R. No. : B-TX-042


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	66.14	65.31	69.92	RIF RESISTANCE DETECTED
	66.35	65.36	69.85	RIF RESISTANCE DETECTED
Sample 2	66.31	71.98	71.98	RIF RESISTANCE NOT DETECTED
	66.51	71.5	70.8	RIF RESISTANCE NOT DETECTED
	66.24	71.49	71.31	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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