



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

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

Date: 03/03/2021

BRAND NAME	Truenat™ MTB-RIF Dx		
GENERIC NAME	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>		
LOT No.	TX060		
MFG. DATE	2021-02		
EXP. DATE	2023-01		
PACK SIZE	5T, 20T, 50T		
STORAGE	2°C to 30°C		A.R. No. : B-TX-060

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 desiccant pouch and 1 filter barrier tip	5 no, 20 no, 50 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	67.51	66.89	69.92	RIF RESISTANCE DETECTED
	66.01	66.19	71.56	RIF RESISTANCE DETECTED
	66.75	66.96	70.45	RIF RESISTANCE DETECTED
	66.41	66.96	70.84	RIF RESISTANCE DETECTED
Sample 2	66.4	72.24	71.03	RIF RESISTANCE NOT DETECTED
	67.31	72.7	70.1	RIF RESISTANCE NOT DETECTED
	65.5	71.2	71.49	RIF RESISTANCE NOT DETECTED
	67.7	72.91	70.17	RIF RESISTANCE NOT DETECTED
	66.41	72.08	70.7	RIF RESISTANCE NOT DETECTED
	67.12	72.71	70.19	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
Name: Dr. Praveen Kumar
Designation: QC Head

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Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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