



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

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

Date: 16-01-2020

BRAND NAME	Truenat™ MTB-RIF Dx		
GENERIC NAME	Chip-based Real Time PCR Test for Rifampicin resistant <i>Mycobacterium tuberculosis</i>		
LOT No.	TX037		
MFG. DATE	2019-09		
EXP. DATE	2021- 08		
PACK SIZE	5T, 20T		
STORAGE	2°C to 30°C		A.R. No. : B-TX-037g

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

PERFORMANCE				
Specificity Tests	Tm		Control	Result
	P1	P2		
Sample 1	65.87	65.34	69.73	RIF RESISTANCE DETECTED
	65.77	65.4	70.29	RIF RESISTANCE DETECTED
Sample 2	66.44	72.44	70.06	RIF RESISTANCE NOT DETECTED
	66.15	72.15	70.82	RIF RESISTANCE NOT DETECTED
	66.24	71.78	70.24	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 Pvt. Ltd.

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

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

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

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