



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:15/07/2022
Doc ID: COA/TN/TX071

BRAND NAME	Truenat [®] MTB-RIF Dx		
GENERIC NAME	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>		
LOT No.	TX071	CHIP LOT NO.	HDLW438
MFG. DATE	2022-03	EXP. DATE	2024-02
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C	A.R. No.:B-TX-071c	


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

PERFORMANCE				
Specificity Tests	Tm		Control	Result
	P1	P2		
Sample 1	66.84	67.32	70.57	RIF RESISTANCE DETECTED
	66.08	66.55	70.7	RIF RESISTANCE DETECTED
	66.94	67.31	69.59	RIF RESISTANCE DETECTED
	67.26	67.35	70.36	RIF RESISTANCE DETECTED
Sample 2	66.13	71.96	70.98	RIF RESISTANCE NOT DETECTED
	66.87	72.59	70.4	RIF RESISTANCE NOT DETECTED
	66.62	71.85	70.19	RIF RESISTANCE NOT DETECTED
	66.93	72.52	70.22	RIF RESISTANCE NOT DETECTED
	67.28	72.77	70.75	RIF RESISTANCE NOT DETECTED
	66.68	72.7	70.22	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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