



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 10/08/2019

BRAND NAME : Truenat™ MTB-RIF Dx

GENERIC NAME: Chip-based Real Time PCR test for Rifampicin resistant *Mycobacterium tuberculosis*

LOT. NO. : TX034

MFG. DATE : 2019- 08

EXP. DATE : 2021- 07

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. NO. : B-TX-034a


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	66.43	71.73	70.91	RIF RESISTANCE NOT DETECTED
	66.42	71.96	71.03	RIF RESISTANCE NOT DETECTED
	66.42	71.87	71.12	RIF RESISTANCE NOT DETECTED
Sample 2	65.71	64.57	71.10	RIF RESISTANCE DETECTED
	65.90	65.25	70.77	RIF RESISTANCE 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. Prajeet Kumar
Designation: QC Head

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