



MOLBIO DIAGNOSTICS PVT. LTD.

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

CERTIFICATE OF ANALYSIS

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

Date: 20/09/2019

BRAND NAME : Truenat™ MTB-RIF Dx

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

LOT. NO. : TX035

MFG. DATE : 2019- 09

EXP. DATE : 2021- 08

PACK SIZE : 5T, 20T

STORAGE : 2°C to 30°C

A.R. NO. : B-TX-035a

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	66.68	72.45	70.45	RIF RESISTANCE NOT DETECTED
	66.47	72.54	70.66	RIF RESISTANCE NOT DETECTED
	66.50	72.73	70.75	RIF RESISTANCE NOT DETECTED
	66.27	72.31	70.7	RIF RESISTANCE NOT DETECTED
	66.94	71.98	71.68	RIF RESISTANCE NOT DETECTED
	66.63	72.26	71.33	RIF RESISTANCE NOT DETECTED
Sample 2	66.34	65.52	71.35	RIF RESISTANCE DETECTED
	66.24	65.87	70.80	RIF RESISTANCE DETECTED
	66.17	64.94	71.05	RIF RESISTANCE DETECTED
	65.94	65.29	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
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Designation: QC Head

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0