



MOLBIO DIAGNOSTICS PVT. LTD.  
An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

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

Date: 15/07/2019

PRODUCT : Truenat™ MTB-RIF Dx  
LOT. NO. : TX032  
MFG. DATE : 2019- 07  
EXP. DATE : 2020- 06  
PACK SIZE : 5T, 20T  
STORAGE : 2°C to 30°C


A.R. NO. : B-TX-032a

**PRECAUTION:** The product is offered without warranty for any other specific use than that specified in the 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 nos, 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

Performance				
Specificity Tests	Tm		Control	Result
	P1	P2		
Sample 1	66.01	71.41	70.84	RIF RESISTANCE NOT DETECTED
	65.89	71.59	70.96	RIF RESISTANCE NOT DETECTED
	66.3	71.89	71.01	RIF RESISTANCE NOT DETECTED
Sample 2	65.78	64.76	70.47	RIF RESISTANCE DETECTED
	66.13	65.38	70.1	RIF RESISTANCE DETECTED

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

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0