



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

**CERTIFICATE OF ANALYSIS**

Mfg. Lic. No. : 874/L

Date: 29/12/2018

**PRODUCT** : Truenat™ MTB-RIF Dx  
**LOT. NO.** : TX018  
**MFG. DATE** : 2018- 10  
**EXP. DATE** : 2020- 09  
**PACK SIZE** : 5T, 20T  
**STORAGE** : 2°C to 30°C

**A.R. NO.** : B-TX-018a

**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	67.14	72.37	66.99	RIF RESISTANCE DETECTED
	66.82	72.35	70.87	RIF RESISTANCE DETECTED
	67.21	72.68	70.24	RIF RESISTANCE DETECTED
	65.84	71.42	71.08	RIF RESISTANCE DETECTED
	66.15	71.99	70.1	RIF RESISTANCE DETECTED

Performance						
Specificity Tests	Specification					
	P1 Tm			P2 Tm		
Positive sample	RIF resistance detected	<65°C>	RIF resistance not detected	RIF resistance detected	<70.5°C>	RIF resistance not 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.**

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