



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

**CERTIFICATE OF ANALYSIS**

Mfg. Lic. No. : 874/L

Date: 16/11/2018

**PRODUCT** : Truenat™ MTB-RIF Dx  
**LOT. NO.** : TX019  
**MFG. DATE** : 2018- 10  
**EXP. DATE** : 2020- 09  
**PACK SIZE** : 5T, 20T  
**STORAGE** : 2°C to 30°C

**A.R. NO.** : B-TX-019a

**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	66.33	71.98	71.45	RIF RESISTANCE NOT DETECTED
	66.68	72.43	71.05	RIF RESISTANCE NOT DETECTED
	66.98	72.4	71.08	RIF RESISTANCE NOT DETECTED
Sample 2	66.52	65.57	70.47	RIF RESISTANCE DETECTED
	66.5	65.76	70.61	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.

**Regd. Office:** H. No. 13, Sagar Society, Dona Paula, Panaji, N. Goa 403 004. INDIA  
**Works:** Plot Nos. M 46-47, Phase III - B, Verna Industrial Estate, Verna - Goa 403 722. INDIA  
**Tel:** 91 832 2783267/6624783 **E mail:** admin@molbiodiagnostics.com  
**Office:** No. UGO-7, Ground Floor, Ambrosia Residency, Cabesa, Alto Santacruz, Goa - 403 005. INDIA  
**Tel:** 91 832 2458111/2458112 **Email:** sales@molbiodiagnostics.com  
**Website:** www.molbiodiagnostics.com **CIN:** U33125GA2000PTC002909