



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

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 21/12/2018

PRODUCT : Truenat™ MTB-RIF Dx  
LOT. NO. : TX017  
MFG. DATE : 2018- 10  
EXP. DATE : 2020- 09  
PACK SIZE : 5T, 20T  
STORAGE : 2°C to 30°C

A.R. NO. : B-TX-017a

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	66.49	65.5	71.54	RIF RESISTANCE DETECTED
	66.14	64.66	70.8	RIF RESISTANCE DETECTED
	66.54	65.08	69.78	RIF RESISTANCE DETECTED
	66.86	65.03	69.92	RIF RESISTANCE DETECTED
	66.45	64.78	70.33	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  
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