



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

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 22/11/2018

PRODUCT : Truenat™ MTB-RIF Dx
LOT. NO. : TX020
MFG. DATE : 2018- 11
EXP. DATE : 2020- 10
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-TX-020a

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	66.82	72.82	70.98	RIF RESISTANCE NOT DETECTED
	66.58	72.23	71.08	RIF RESISTANCE NOT DETECTED
	66.49	70.87	71.77	RIF RESISTANCE NOT DETECTED
Sample 2	66.21	65.1	71.75	RIF RESISTANCE DETECTED
	65.82	65.33	72.56	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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Designation: QC Head

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