

Licence no.: MFG/IVD/2019/000018

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Product Name	Truenat® MTB-RIF Dx		
Generic Name Chip-based Real Time PCR Test for Rifampicin Resistan Mycobacterium tuberculosis			
Lot No.	TX086R		
Set No.	g		
Mfg. Date	2022-11		
Exp. Date	2024-10		
Pack Size	5T, 20T		
Storage condition	2°C to 30°C		

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation Present Present	
01	Number of pouches as per pack size	Should be present		
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present		
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour	
04	Package Insert	Should be present	Present	
05	Seal integrity test	Should pass	Pass	

Ct Values			Results	
Tm		Control		
P2	P1			
6.81 <u>+</u> 0.25	66.77 <u>+</u> 0.31	70.33 <u>+</u> 0.62	RIF Resistance detected	
2.27 <u>+</u> 0.55	66.66 <u>+</u> 0.31	70.31 <u>+</u> 0.40	RIF Resistance not detected	
2.27 <u>+</u> 0.55	66.57 <u>+</u> 0.30	70.12 <u>+</u> 0.21	RIF Resistance not detected	
	P2 6.81 ± 0.25 2.27 ± 0.55 2.27 ± 0.55	P2 P1 6.81 ± 0.25 66.77 ± 0.31 2.27 ± 0.55 66.66 ± 0.31	P2 P1 6.81 ± 0.25 66.77 ± 0.31 70.33 ± 0.62 2.27 ± 0.55 66.66 ± 0.31 70.31 ± 0.40 2.27 ± 0.55 66.57 ± 0.30 70.12 ± 0.21	

*Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices, RIF-Rifampicin Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.

Name : Dr. Praveen Kumar Department: Quality Control Designation: QC Head

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