

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 Resistant Mycobacterium tuberculosis		
Lot No.	TX085 R		
Set No.	d		
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	
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	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	

Pei	rformance testi	ng data		
Ct Values			Results	
Tm		Control		
P2	P1	W.		
69.95 ± 0.24	67.17 ± 0.24	70.26 ± 0.40	RIF Resistance detected	
72.26 ± 0.45	66.99 ± 1.36	70.53 ± 0.43	RIF Resistance not detected	
72.29 ± 0.46	66.87 ± 0.40	70.07 ± 0.44	RIF Resistance not detected	
	P2 69.95 ± 0.24 72.26 ± 0.45	Ct Values Tm P2 P1 69.95 ± 0.24 67.17 ± 0.24 72.26 ± 0.45 66.99 ± 1.36	TmControlP2P1 70.26 ± 0.40 69.95 ± 0.24 67.17 ± 0.24 70.26 ± 0.40 72.26 ± 0.45 66.99 ± 1.36 70.53 ± 0.43	

*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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