

Licence no.: MFG/IVD/2021/000071

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Product Name	Truenat® MTB		
Generic Name Chip-based Real Time PCR Test for Mycobacterium to			
Lot No.	049TB		
Set No.	b		
Mfg. Date	2023-12		
Exp. Date	2025-11		
Pack Size	5T, 20T, 50T		
Storage condition	2°C to 30°C		

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	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

Performance testing data				
	Ct Values			
Samples	MTB	Control		
Non Template Control	ND	ND		
Negative Sample	ND	31.08 ± 0.93		
Positive sample 1	26.76 ± 0.30	28.85 ± 0.54		
Positive sample 2	30.32 ± 1.02	27.22 ± 0.24		
Positive Sample 3	23.18 ± 0.16	27.23 ± 0.31		
ND - Not detected, Ct- Cycle threshold				

^{*}Mfg- Manufacturing, Exp- Expiry, GMP- Good Manufacturing Practices

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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