

ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

Mfg. Lic. No.: MFG/IVD/2019/000018

Date:17/06/2022  
Doc ID: COA/TN/TX076

<b>BRAND NAME</b>	Truenat <sup>®</sup> MTB-RIF Dx		
<b>GENERIC NAME</b>	Chip-based Real Time PCR Test for Rifampicin Resistant <i>Mycobacterium tuberculosis</i>		
<b>LOT No.</b>	TX076	<b>CHIP LOT NO.</b>	HDLW419
<b>MFG. DATE</b>	2022-06	<b>EXP. DATE</b>	2024-05
<b>PACK SIZE</b>	5T, 20T, 25T, 50T		
<b>STORAGE</b>	2°C to 30°C		<b>A.R. No.:</b> B-TX-076b


**PRECAUTION:** Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 25 no 50 no.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE				
Specificity Tests	Tm		Control	Result
	P1	P2		
Sample 1	66.82	67.03	69.94	RIF RESISTANCE DETECTED
	66.47	66.47	70.13	RIF RESISTANCE DETECTED
	66.38	66.57	70.03	RIF RESISTANCE DETECTED
	66.43	66.43	70.1	RIF RESISTANCE DETECTED
Sample 2	66.31	71.9	70.84	RIF RESISTANCE NOT DETECTED
	66.49	72.19	70.57	RIF RESISTANCE NOT DETECTED
	66.36	71.64	70.47	RIF RESISTANCE NOT DETECTED
	66.33	71.96	70.36	RIF RESISTANCE NOT DETECTED
	66.57	72.5	70.33	RIF RESISTANCE NOT DETECTED
	67	71.86	70.06	RIF RESISTANCE NOT DETECTED

\*Tm-Melting temperature, RIF-Rifampicin

**MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE**

  
**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
Designation: QC Head  
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