

MOLBIO DIAGNOSTICS PRIVATE LIMITED ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 04/07/2022 Doc ID:COA/TN/CG023

BRAND NAME	Truenat® Chikungunya				
GENERIC NAME	Chip-based Real Time PCR Test for Chikungunya				
LOT No.	CG023	CHIP LOT No.	¥	HDLW	/431
MFG. DATE	2022-06	EXP. DATE		2024-	05
PACK SIZE	5T, 20T, 25T, 50				
STORAGE	2°C to 30°C		A.	R. No.	: B-CG-023a

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

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

PERFORMA	NCE		
CONTROLS	(Ct Values)		
Specificity Tests	Chikungunya	Contro	
Negative Control	ND	27.5	
·	28.33	24.33	
Positive Control	28.83	24	
	28.33	24	
	29.11	24.14	
Average	28.65	24.12	
Standard deviation	<u>+</u> 0.39	<u>+</u> 0.16	

^{*}ND- Not detected, Ct- Cycle threshold

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

QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head
Rage 1 of 1

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^{*}A deviation of =<1.5 is acceptable for Ct values