

MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 17/09/2021
Doc ID:COA/TN/CG021

BRAND NAME	Truenat® Chikungunya
GENERIC NAME	Chip-based Real Time PCR Test for Chikungunya
LOT No.	CG021
MFG. DATE	2021-09
EXP. DATE	2023-08
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-CG-021	

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 desiccant pouch and 1 filter barrier tip	5 no, 20 no 50 no.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

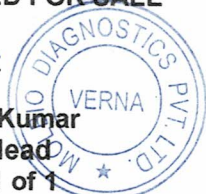
PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	CHK	Control
Negative Control	ND	27.5
	ND	27.75
Positive Control	29.29	27.6
	28.86	26.67
	28.75	27.5
	29.6	28
	29.11	27.25
	29	27.13
	29.13	27.13
	30	27.43
Standard deviation	± 0.41	± 0.39

*ND- Not detected, Ct- Cycle threshold, CHK- Chikungunya

*A deviation of ≤ 1.5 is acceptable for Ct values

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
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Molbio Diagnostics Private Limited

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