



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date: 29/09/2020

BRAND NAME	Truenat™ Chikungunya
GENERIC NAME	Chip-based Real Time PCR Test for Chikungunya
LOT No.	CG016
MFG. DATE	2020-09
EXP. DATE	2022-08
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-CG-016	

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.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	CHK	Control
Negative Control	ND	30.67
Positive Control	28.5	28.8
	28.5	29.29
	28.67	29.8
	28.2	29.33
Standard deviation	± 0.19	± 0.40

*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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