



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 21/02/2021

BRAND NAME	Truenat™ Dengue/Chikungunya
GENERIC NAME	Chip-based Real Time Duplex PCR Test for Dengue and Chikungunya
LOT No.	DC014
MFG. DATE	2020-12
EXP. DATE	2022-11
PACK SIZE	5T, 20T, 50 T
STORAGE	2°C to 30°C
A.R. No. : B-DC-014	

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	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE				
Sr. No.	CONTROLS	Test Lot (Ct Values)		
	Specificity Tests	DEN	CHK	Control
	Negative Control	ND	ND	27.5
	Positive Control (DEN)	29	ND	27.25
	Positive Control (CHK)	ND	28.14	28.33
	Positive Control (DEN/CHK)	25.25	26.25	26.17
		25.75	25.33	25
	Standard deviation	± 0.35	±0.65	± 0.82

*ND- Not detected, Ct- Cycle threshold, DEN-Dengue, 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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