



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/10/2021
DOC ID:COA/TN/DC016

BRAND NAME	Truenat [®] Dengue/Chikungunya
GENERIC NAME	Chip-based Real Time Duplex PCR Test for Dengue and Chikungunya
LOT No.	DC016
MFG. DATE	2021-10
EXP. DATE	2023-009
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C

A.R. No. : B-DC-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 dessicant 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				
Sr. No.	CONTROLS	Test Lot(Ct Values)		
Specificity Tests		DEN	CHK	Control
Negative Control		ND	ND	27.57
		ND	ND	27.75
Positive Control (DEN)		28.2	ND	30
		28	ND	30
Positive Control (CHK)		ND	30.2	30
		ND	30.8	29
Positive Control (DEN/CHK)		29.5	29.75	28.75
		28.6	29.67	29
		29.6	29.8	29.8
		29.4	29.6	29.75
Standard deviation		+ 0.45	+0.08	+ 0.52

*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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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0