



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 27/02/2021

BRAND NAME	Truenat™ Dengue	
GENERIC NAME	Chip-based Real Time PCR Test for Dengue	
LOT No.	DN025	
MFG. DATE	2020-11	
EXP. DATE	2022-10	
PACK SIZE	5T, 20T, 50T	
STORAGE	2°C to 30°C	A.R. No. : B-DN-025

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

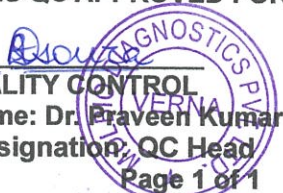
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 no, 20 no, 50 no	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	DEN	Control
Negative Control	ND	27.14
Positive Control	29.75	27.0
	28.17	26.22
	29.29	26.43
	29.14	27.0
Standard deviation	± 0.66	± 0.39

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

*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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