

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

Licence No.: MFG/IVD/2019/000018

Date: 05/07/2025

Document ID: COA/TN/DN045/5T

Product Name	Truenat [®] Dengue
Generic Name	Chip-based Real Time PCR Test for Dengue
Lot No.	DN045
Set No.	NA
Mfg. Date	2025-05
Exp. Date	2027-04
Pack Size	5T
Storage condition	2°C to 30°C

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

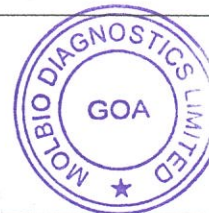
Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data		
Samples	Ct Values	
	Dengue	Control
Non Template Control	ND	ND
Negative Sample	ND	26.55 ± 0.50
Positive sample 1	22.38 ± 0.22	26.57 ± 0.29
Positive sample 2	26.50 ± 0.38	28.00 ± 0.57
Positive Sample 3	30.21 ± 0.82	27.66 ± 0.86

ND – Not detected, Ct- Cycle threshold

*Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.



for Name : Dr. Praveen Kumar
Department: Quality Control
Designation: QC Head

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License No.: MFG/IVD/2019/000003

Date: 06/07/2025

Doc ID: COA/TP/ATM110/50T

Product Name	Trueprep [®] AUTO Transport Medium for Swab Specimen Pack
Generic Name	Medium for Collection, Decontamination and Transport of Swab Specimen for Trueprep [®] AUTO
Lot No.	ATM110
Mfg. Date	2025-07
Exp. Date	2027-06
Pack Size	50T
Storage condition	2°C to 40°C

PRECAUTION: Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep[®] AUTO Transport Medium for Swab Specimen Pack)	(Present (P)/Not Present (NP))	
1	Transport Medium for Swab Specimen Tubes	Present	Present
2	Package Insert	Present	Present

Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1 E.gene (Average)	Test 2 Orf1A (Average)	IC (Average)
Negative Control						
1	Negative COVID-19	ND	Control should be detected	ND	ND	24.97
Positive Control						
1	Positive COVID-19	Test and Control should be detected		21.89	22.54	23.40
Non Template Control Test for COVID-19						
1	NTC	Test 1, Test 2 and Control should not be detected		ND	ND	ND

*Ct-Cycle Threshold *IC- Internal Control *ND- Not Detected *NA- Not Applicable *NTC- Non Template Control

The lot is tested and verified as per QC Standards and is approved.

for 
Name: Dr.Praveen Kumar MK
Department: Quality Control
Designation: QC Head