



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 07-01-2019

PRODUCT : Truenat™ Dengue
LOT. NO. : DN017
MFG. DATE : 2019- 01
EXP. DATE : 2020- 12
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-DN-017a

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the 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 nos, 20 nos.	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	IC
Negative Control		ND	26.5
Positive Control		26	26
		26.8	27.8
		28.14	28.8
		28.25	27.5
Standard deviation		± 1.08	± 1.15

*ND- Not detected

*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 RELEASED FOR SALE



QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

Page 1 of 1

Molbio Diagnostics Pvt. Ltd.

Regd. Office: H. No. 13, Sagar Society, Dona Paula, Panaji, N. Goa 403 004. INDIA

Works. Plot Nos. M 46-47, Phase III - B, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: 91 832 2783267/6624783 E mail: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909