



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 14-03-2018

PRODUCT : Truenat™ Chikungunya
LOT. NO. : CG012
MFG. DATE : 2018- 02
EXP. DATE : 2020- 01
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-CG-012

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 contain 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	01no.	Pass

Performance			
Sr. No.	CONTROLS	Test Lot (Ct Values)	
Specificity Tests		CG	IC
Negative Control		ND	30.6
Positive Control		29.21	28.08
		29	28
		28.33	29.2
Standard deviation		± 0.22	± 0.75

*ND- Not detected

*A deviation of ± 1 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

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