



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : 874/L

Date: 25/05/2018

PRODUCT : Truenat™ CT/NG
LOT. NO. : NC007
MFG. DATE : 2018- 04
EXP. DATE : 2020- 03
PACK SIZE : 5T, 20T
STORAGE : 2°C to 30°C

A.R. NO. : B-NC-007

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		CT	NG	IC
Negative Control		ND	ND	27.1
Positive Control		31.2	29.38	26
		32	30.4	27.43
		30	29.17	26.13
		30.2	28.8	26.25
Standard deviation		± 0.92	± 0.68	± 0.65

*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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