



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

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

Date: 13-02-2020

BRAND NAME	Truenat™ NG
GENERIC NAME	Chip-based Real Time PCR Test for <i>Neisseria gonorrhoeae</i>
LOT No.	NG012
MFG. DATE	2020- 02
EXP. DATE	2022- 01
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-NG-012a	

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.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	NEG	Control
Negative Control	ND	30.43
Positive Control	29.29	31.17
	29.8	30.5
	29.33	30.57
	29.17	30.4
Standard deviation	± 0.27	± 0.34

\*ND- Not detected, Ct- Cycle threshold, NEG- *Neisseria gonorrhoeae*

\*A deviation of  $\leq 1.5$  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 Pvt. Ltd.**

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