



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date:01/10/2022

Doc ID: COA/TN/NG019a

BRAND NAME	Truenat [®] NG		
GENERIC NAME	Chip-based Real Time PCR Test for <i>Neisseria gonorrhoeae</i>		
LOT No.	NG019	CHIP LOT NO.	HDLW469
MFG. DATE	2022-09	EXP. DATE	2024-08
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No.:B-NG-019a

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,25 no. 50 nos.	Pass
2	Colour of desiccant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	NG	Control
Negative Control	ND	27.6
Positive Control	30	25
	29.16	24.43
	29	25
	28.43	24.57
Average	29.43	25.79
Standard deviation	± 0.46	± 0.25

*ND- Not detected, Ct- Cycle threshold, NG-*Neisseria gonorrhoeae*

*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 QC APPROVED FOR SALE



QUALITY CONTROL

Name: Dr. Praveen Kumar

Designation: QC Head

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Molbio Diagnostics Private Limited

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