



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 14/06/2022
Doc ID: COA/TN/NC018

BRAND NAME	Truenat [®] CT/NG		
GENERIC NAME	Chip-based Real Time Duplex PCR Test for <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i>		
LOT No.	NC018	CHIP LOT NO.	HDLW415
MFG. DATE	2022-06	EXP. DATE	2024-05
PACK SIZE	5T, 20T, 25T, 50T		
STORAGE	2°C to 30°C		A.R. No. : B-NC-018a

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 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 25no, 50no.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

PERFORMANCE			
CONTROLS	(Ct Values)		
Specificity Tests	CT	NG	Control
Negative Control	ND	ND	29.38
Positive Control (NG)	ND	30.2	25.5
Positive Control (CT)	27.75	ND	25.43
Positive Control (CT/NG)	29.29	27.14	24.4
	31.29	27.75	25.0
Average	30.29	27.44	24.7
Standard deviation	+1.41	+0.43	+0.42

*ND- Not detected, Ct- Cycle threshold, CT-*Chlamydia trachomatis*, 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

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

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

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