



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 05/05/2021  
Doc ID: COA/TN/CT016

BRAND NAME	Truenat™ CT
GENERIC NAME	Chip-based Real Time PCR Test for <i>Chlamydia trachomatis</i>
LOT No.	CT016
MFG. DATE	2021-04
EXP. DATE	2023-03
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-CT-016	

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

PERFORMANCE		
CONTROLS	(Ct Values)	
Specificity Tests	CLT	Control
Negative Control	ND	28.17
Positive Control	25.8	28.4
	26.33	28.0
	26.29	27.6
	27.0	28.67
Standard deviation	± 0.49	± 0.46

\*ND- Not detected, Ct- Cycle threshold, CLT- *Chlamydia trachomatis*

\*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. Praveer Kumar  
Designation: QC Head

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## Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO