



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 22/04/2021

Doc ID: COA/TN/CT014

BRAND NAME	Truenat™ CT
GENERIC NAME	Chip-based Real Time PCR Test for <i>Chlamydia trachomatis</i>
LOT No.	CT014
MFG. DATE	2021-04
EXP. DATE	2023-03
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-CT-014	

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)	
	CLT	Control
Specificity Tests		
Negative Control	ND	29.29
Positive Control	28	28
	28.8	27
	30.33	27.8
	28.14	27.6
Standard deviation	± 1.06	± 0.43

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

*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


For **QUALITY CONTROL**
Name: Dr. Praveen Kumar



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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO