



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 06/05/2021

Doc ID: COA/TN/CT017

BRAND NAME	Truenat™ CT
GENERIC NAME	Chip-based Real Time PCR Test for <i>Chlamydia trachomatis</i>
LOT No.	CT017
MFG. DATE	2021-04
EXP. DATE	2023-03
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-CT-017	

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	29.6
Positive Control	26.5	28.67
	26.13	28.14
	26.4	28.13
	24.8	28.29
Standard deviation	± 0.78	± 0.25

\*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. Praveen Kumar  
Designation: QC Head  
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Molbio Diagnostics Private Limited

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