



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2019/000003

Date:05/09/2024  
Doc ID: COA/TN/PCIII016

BRAND NAME	Truenat <sup>®</sup> Positive Control Kit - Panel III		
GENERIC NAME	Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: CT, NG, Trich, HPV- <sub>HR</sub> , GBS and Salmonella		
LOT NO	PCIII016		
MFG. DATE	2024-08		
EXP. DATE	2025-07		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIII-016

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Negative control	Present	Present
2	Positive control (08- strip tubes containing dried down positive control)	Present	Present
3	Package insert	Present	Present

Observation (Ct Value)			
Sr. No.	Truenat <sup>®</sup> test name	Positive control	Negative control
1	CT	26.89 ± 0.57	ND
2	NG	26.66 ± 0.58	ND
3	Trich	28.46 ± 0.32	ND
4	HPV- <sub>HR</sub>	HP16/31: 27.43 ± 0.42 HP18/45: 26.71 ± 0.62	HP16/31: ND HP18/45: ND
5	GBS	26.87 ± 0.40	ND
6	Salmonella	27.33 ± 0.47	ND

\*ND- Not detected, Ct- Cycle threshold, RIF- Rifampicin, NA- Not Applicable

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

The lot is tested and verified as per QC standards and is approved

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head



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Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO