



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 26/10/2024
Doc ID: COA/TN/PCIII017

BRAND NAME	Truenat® Positive Control Kit - Panel III		
GENERIC NAME	Control Kit for Truenat® Chip-based micro PCR Tests: CT, NG, Trich, HPV- _{HR} , GBS and Salmonella		
LOT NO	PCIII017		
MFG. DATE	2024-10		
EXP. DATE	2025-09		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIII-017

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® test name	Positive control	Negative control
1	CT	27.79 ± 0.50	ND
2	NG	26.03 ± 0.55	ND
3	Trich	29.17 ± 0.58	ND
4	HPV- _{HR}	HP16/31: 25.77 ± 0.25 HP18/45: 25.73 ± 0.23	HP16/31: ND HP18/45: ND
5	GBS	28.25 ± 0.18	ND
6	Salmonella	26.99 ± 0.20	ND

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

*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 RELEASED FOR SALE


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



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Molbio Diagnostics Private Limited

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