

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 09/06/2025

Doc ID: COA/TN/PCIII020

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	PCIII020		
MFG. DATE	2025-05		
EXP. DATE	2026-04		
PACK SIZE	08T		
STORAGE	2°C to 40°C		A.R. No. : B-PCIII-020

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	27.95 ± 0.83	ND
2	NG	27.36 ± 0.1	ND
3	Trich	28.07 ± 0.28	ND
4	HPV-HR	HP16/31: 26.25 ± 0.16 HP18/45: 27.17 ± 0.29	HP16/31: ND HP18/45: ND
5	GBS	26.25 ± 0.18	ND
6	Salmonella	27.24 ± 0.22	ND

*ND- Not detected, Ct- Cycle threshold, 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 LOT IS RELEASED FOR SALE

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