

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 04/11/2025

Doc ID: COA/TN/PCIII022

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	PCIII022
MFG. DATE	2025-11
EXP. DATE	2026-10
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCIII-022	

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	26.67 ± 0.29	ND
2	NG	28.31 ± 0.39	ND
3	Trich	27.29 ± 0.43	ND
4	HPV-HR	HP16/31: 26.66 ± 0.36 HP18/45: 27.27 ± 0.35	HP16/31: ND HP18/45: ND
5	GBS	27.94 ± 0.60	ND
6	Salmonella	26.68 ± 0.16	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

