

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/01/2025

Doc ID: COA/TN/PCIII018

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	PCIII018
MFG. DATE	2025-01
EXP. DATE	2025-12
PACK SIZE	08T
STORAGE	2°C to 40°C
A.R. No. : B-PCIII-018	

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

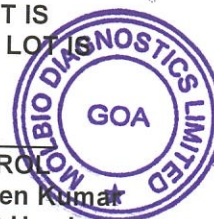
Observation (Ct Value)			
Sr. No.	Truenat [®] test name	Positive control	Negative control
1	CT	27.26 ± 0.74	ND
2	NG	27.50 ± 0.50	ND
3	Trich	27.22 ± 0.10	ND
4	HPV- _{HR}	HP16/31: 26.47 ± 0.29 HP18/45: 26.24 ± 0.08	HP16/31: ND HP18/45: ND
5	GBS	27.69 ± 0.65	ND
6	Salmonella	27.19 ± 0.22	ND

*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 LOT IS RELEASED FOR SALE

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



Page 1 of 1