

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date: 24/04/2025**

**Doc ID: COA/TN/PCIII019**

<b>BRAND NAME</b>	Truenat <sup>®</sup> Positive Control Kit - Panel III
<b>GENERIC NAME</b>	Control Kit for Truenat <sup>®</sup> Chip-based micro PCR Tests: CT, NG, Trich, HPV-HR, GBS and Salmonella
<b>LOT NO</b>	PCIII019
<b>MFG. DATE</b>	2025-04
<b>EXP. DATE</b>	2026-03
<b>PACK SIZE</b>	08T
<b>STORAGE</b>	2°C to 40°C
<b>A.R. No. : B-PCIII-019</b>	

**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	28.13 ± 0.59	ND
2	NG	27.60 ± 0.50	ND
3	Trich	28.42 ± 0.03	ND
4	HPV-HR	HP16/31: 27.25 ± 0.25 HP18/45: 27.15 ± 0.17	HP16/31: ND HP18/45: ND
5	GBS	28.46 ± 1.22	ND
6	Salmonella	27.32 ± 0.29	ND

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

\*A deviation of  $\leq 1.5$  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**

*pkc*

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