



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : MFG/IVD/2019/000018

Date: 10/02/2022
Doc ID: COA/TN/HP013

BRAND NAME	Truenat [®] HPV- _{HR}
GENERIC NAME	Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16, 31 and 18, 45
LOT NO.	HP013
MFG. DATE	2022-02
EXP. DATE	2024-01
PACK SIZE	5T, 20T, 25T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HP-013	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.


Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 50 no.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

Performance			
CONTROLS	Ct Values		
	HPV 16/31	HPV 18/45	Control
Specificity Tests			
Negative Control	ND	ND	27.13
Positive Control (HPV 16/31)	29.2	ND	27.2
Positive Control (HPV 18/45)	ND	27.89	29.11
Positive Control (HPV 16/31 and HPV 18/45)	31.11	30.8	29.67
	30.67	31.19	28.8
Standard deviation	±0.31	±0.27	±0.61

*ND- Not detected, Ct- Cycle threshold, HPV- Human Papillomavirus

*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 QC APPROVED FOR SALE


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

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO