



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 27/10/2021
Doc ID: COA/TN/HP012

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.	HP012
MFG. DATE	2021-06
EXP. DATE	2023-05
PACK SIZE	5T, 20T, 50T
STORAGE	2°C to 30°C
A.R. No. : B-HP-012	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

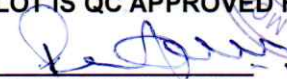
Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 dessicant pouch and 1 filter barrier tip	5 no, 20 no, 50 no.	Pass
2	Colour of dessicant pouch	Orange	Pass
3	Package insert	01 no.	Pass

Performance			
CONTROLS	Ct Values		
	HPV 16/31	HPV 18/45	Control
Specificity Tests			
Negative Control	ND	ND	31.6
Positive Control (HPV 16/31)	27.0	ND	29.25
Positive Control (HPV 18/45)	ND	27.57	31.2
Positive Control (HPV 16/31 and HPV 18/45)	26.6	28.0	30.75
	27.33	28.29	31.0
Standard deviation	+0.51	+0.20	+0.17

*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

Page 1 of 1

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