



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 12/10/2020

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.	HP008		
MFG. DATE	2020-09		
EXP. DATE	2022-08		
PACK SIZE	5T, 20T		
STORAGE	2°C to 30°C		A.R. No. : B-HP-008

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 desiccant pouch and 1 filter barrier tip	5 no, 20 no.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

Performance			
CONTROLS	Test Lot (Ct Values)		
	HPV 16/31	HPV 18/45	Control
Specificity Tests			
Negative Control	ND	ND	29.8
Positive Control (HPV 16/31)	25.17	ND	30.6
Positive Control (HPV18/45)	ND	25.33	30.14
Positive Control (HPV 16/31 and HPV 18/45)	25.5	26	30.8
	25.6	26	30.67
Standard deviation	0.07	0.0	0.09

*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

For



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@molbiodiagnosics.com

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO