



**MOLBIO DIAGNOSTICS PVT. LTD.**

**An ISO 9001 & ISO 13485 certified company**

**CERTIFICATE OF ANALYSIS**

**Mfg. Lic. No. : 874/L**

**Date: 14/06/2018**

**PRODUCT : Truenat™ HPV<sub>HR</sub>**  
**LOT. NO. : HP004**  
**MFG. DATE : 2018- 05**  
**EXP. DATE : 2020- 04**  
**PACK SIZE : 5T, 20T**  
**STORAGE : 2°C to 30°C**

**A.R. NO. : B-HP-004**

**PRECAUTION:** The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contain 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 nos, 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01no.	Pass

Performance			
CONTROLS	Test Lot (Ct Values)		
	HPV 16/31	HPV 18/45	IC
Specificity Tests			
Negative Control	ND	ND	29.6
Positive Control	32	30.33	30.8
	31.33	31.17	30.14
	32.2	31.67	31.4
	32.43	32.14	30.33
Standard deviation	± 0.47	± 0.77	± 0.56

\*ND- Not detected

\*A deviation of  $\pm 1$  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

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