



**MOLBIO DIAGNOSTICS PVT. LTD.**

**An ISO 9001 & ISO 13485 Certified company**

**CERTIFICATE OF ANALYSIS**

**Mfg. Lic. No. : 3800/TEST/MFG/2017**

**Date: 30-11-2018**

**PRODUCT :Truenat™ HIV-1**

**LOT. NO. : THI18**

**MFG. DATE : 2018-11**

**EXP. DATE : 2020- 10**

**PACK SIZE : 5T, 20T**

**STORAGE : 2°C to 30°C**

**A.R. NO. : B-THI-18**

**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 contains 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	01 no.	Pass

Performance			
Sr. No.	CONTROLS	Test Lot (Ct Values)	
Specificity Tests		HIV-1	Control
Negative Control		ND	32
Positive Control		28.13	29.14
		30.11	30.38
		27.33	29
		29.08	29.9
Standard deviation		± 1.20	± 0.65

\*ND- Not detected

\*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 QC APPROVED FOR EXAMINATION TEST OF ANALYSIS.**



**QUALITY CONTROL**

**Name: Dr. Praveen Kumar**

**Designation: QC Head**

Page 1 of 1

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