



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 Certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No. : MFG/TL/IVD/2019/000001

Date: 21-02-2020

BRAND NAME	Truenat™ HIV-1
GENERIC NAME	Chip-based Real Time PCR Test for HIV-1 Virus
LOT No.	EHV31
MFG. DATE	2020-02
EXP. DATE	2022-01
PACK SIZE	5T, 20T
STORAGE	2°C to 30°C
A.R. No. : B-EHV-31	

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	(Ct Values)	
Specificity Tests	HIV-1	Control
Negative Control	ND	30.75
Positive Control	28	26.20
	28	27.14
	28.60	26.14
	28.25	26.57
Standard deviation	± 0.28	± 0.45

\*ND- Not detected, Ct- Cycle threshold, HIV-1- Human Immunodeficiency Virus type 1

\*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 TESTING PURPOSE

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head  
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**Molbio Diagnostics Pvt. Ltd.**

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