

## **Molbio Diagnostics Limited**

(Formerly Molbio Diagnostics Private Limited) L-46, Phase II D, Verna Industrial Estate Verna, Goa-403722, India

## MOLBIO DIAGNOSTICS LIMITED \*\* 91832 6724888 \*\* www.molbiodiagnostics.com EN ISO 13485:2016 certified company **CERTIFICATE OF ANALYSIS**

Licence no.: MFG/IVD/2019/000018

Date: 03/07/2025

Document ID:COA/TN/VH014/5T

Product Name	Truenat® HIV-1/HIV-2	
Generic Name	Chip-based Real Time Duplex PCR Test for HIV-1/HIV-2	
Lot No.	VH014	
Set No.	NA	
Mfg. Date	2025-02	
Exp. Date	2027-01	
Pack Size	5T	
Storage condition	2°C to 30°C	

PRECAUTION: Refer Safety Data Sheet and Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
01	Number of pouches as per pack size	Should be present	Present
02	Pouches Contents: 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	Should be present	Present
03	Colour of desiccant pouch	Should be present and Orange in Colour	Present / Orange Colour
04	Package Insert	Should be present	Present
05	Seal integrity test	Should pass	Pass

Performance testing data					
	Ct Values				
Samples	HIV-1	HIV-2	Control		
Non Template Control	ND	ND	ND		
Negative Sample	ND	ND	26.05 ± 0.34		
Positive Sample 1	30.67 ± 0.51	ND	27.55 ± 0.61		
Positive Sample 2	ND	26.10 ± 0.29	26.90 ± 0.28		
Positive Sample 3	29.10 ± 0.94	27.16 ± 1.31	26.80 ± 0.65		
ID - Not detected Ct- Cycle threshold		·	many and Manual Co. 1 in the co.		

<sup>\*</sup>Mfg- Manufacturing, Exp- Expiry

The lot is tested and verified as per QC Standards and is approved.

Name : Dr. Praveen Kurnar **Department: Quality Control Designation: QC Head** 

FM/QT/219-03

Page 1 of 1