



MOLBIO DIAGNOSTICS PVT. LTD.  
An ISO 9001:2015 & ISO 13485:2016 certified company

## CERTIFICATE OF ANALYSIS

Mfg.Lic. No. : MFG/IVD/2019/000003

Date: 15/11/2019

<b>PRODUCT : Trueprep™ AUTO Universal Sample Pre-treatment Pack</b>	
Trueprep™ AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT025 Mfg Date: 2019-11 Exp Date: 2021-10
	A.R. No.: B-USPT-025
Pack size : 20 TESTS, 5 TESTS	STORAGE : 2°C to 40°C

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep™ AUTO Universal Sample Pre-treatment Pack)(Present (P)/Not Present (NP))	(Present (P)/ Not Present (NP))	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1ml)	Present	Present

Performance on Truelab™ micro PCR Analyzers					
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
<b>Negative Control</b>					
1	Neg HBV	ND	Control should be detected	ND	29.17
<b>Positive Control</b>					
1	Pos HCV	Test and Control should be detected		31.33	29.38
2	Pos HIV	Test and Control should be detected		29	29.6
3	Pos HCV	Test and Control should be detected		30.78	30.11

\*Ct- Cycle threshold

\*IC- Internal Control

\*ND- Not Detected

**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

## Molbio Diagnostics Pvt. Ltd.

Regd. Office: H. No. 13, Sagar Society, Dona Paula, Panaji, N. Goa 403 004. INDIA  
Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA  
Tel: 91 832 2783267 E mail: admin@molbiodiagnostics.com  
Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com  
CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E120