



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 14/01/2022

Doc.ID: COA/TP/USPT237

Product: Trueprep® AUTO Universal Sample Pre-treatment Pack		
Lot No.: USPT237	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-USPT-237

**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	Package Insert	Present	Present
3	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	Negative HCV	ND	Control should be detected	ND	28.6
2	Negative COVID-19	ND	Control should be detected	ND	26.0
<b>Positive Control</b>					
1	Positive HBV	Test and Control should be detected		28.14	30.57
2	Positive HBV	Test and Control should be detected		28.43	29.5
3	Positive HCV	Test and Control should be detected		30.33	30.14
4	Positive HIV	Test and Control should be detected		30.08	29.67
5	Positive HIV	Test and Control should be detected		29.17	29.33
6	Positive COVID-19	Test and Control should be detected		30.17	23.6

\*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

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