



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 01/01/2022

Doc.ID: COA/TP/USPT232

<b>Product: Trueprep<sup>®</sup> AUTO Universal Sample Pre-treatment Pack</b>		
<b>Lot No.: USPT232</b>	<b>Mfg. Date: 2021-12</b>	<b>Exp. Date: 2023-11</b>
<b>Pack size: 50T, 20T, 5T</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-USPT-232</b>

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

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

Performance on Truelab <sup>®</sup> micro PCR Analyzers					
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
1	<b>Specificity Tests</b>	<b>Test</b>	<b>IC</b>	<b>Test</b>	<b>IC</b>
<b>Negative Control</b>					
1	Negative HBV	ND	Control should be detected	ND	29.5
2	Negative COVID-19	ND	Control should be detected	ND	25.8
3	Negative HIV	ND	Control should be detected	ND	28.75
<b>Positive Control</b>					
1	Positive HBV	Test and Control should be detected		28.5	30.07
2	Positive HBV	Test and Control should be detected		29.0	28.5
3	Positive HCV	Test and Control should be detected		27.25	29.57
4	Positive HCV	Test and Control should be detected		27.71	30.8
5	Positive HIV	Test and Control should be detected		28.0	29.17

\*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

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