



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date:15/09/2021

Doc.ID:COA/TP/USPT221

Product: Trueprep® AUTO Universal Sample Pre-treatment Pack		
Lot No.: USPT221	Mfg Date: 2021-06	Exp Date: 2023-05
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-USPT-221

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
Negative Control					
1	Negative HBV	ND	Control should be detected	ND	27.0
2	Negative COVID-19	ND	Control should be detected	ND	26.33
Positive Control					
1	Positive HIV	Test and Control should be detected		29.0	27.8
2	Positive HCV	Test and Control should be detected		27.86	30.0
3	Positive HCV	Test and Control should be detected		28.13	30.75
4	Positive HBV	Test and Control should be detected		29.0	27.0
5	Positive HBV	Test and Control should be detected		29.14	27.5
6	Positive COVID-19	Test and Control should be detected		29.13	22.14

*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
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