

CERTIFICATE OF ANALYSIS

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

Date: 16/02/2022

Doc.ID: COA/TP/USPT243

Product: Trueprep[®] AUTO Universal Sample Pre-treatment Pack		
Lot No.: USPT243	Mfg. Date: 2022-02	Exp. Date: 2024-01
Pack size: 50T, 25T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-USPT-242

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 1	Test 2	IC
Negative Control						
1	Negative HCV	ND	Control should be detected	ND	NA	29.5
2	Negative COVID-19			E.gene:ND	Orf1A:ND	26.67
Positive Control						
1	Positive HBV	Test and Control should be detected		28.2	NA	29.11
2	Positive HBV	Test and Control should be detected		27.83	NA	28.17
3	Positive HCV	Test and Control should be detected		27.78	NA	27.25
4	Positive HCV	Test and Control should be detected		27.14	NA	28.0
5	Positive HIV	Test and Control should be detected		29.8	NA	28.57
6	Positive COVID-19	Test and Control should be detected		E.gene:28.75	Orf1A:29.0	23

*Ct- Cycle threshold *IC- Internal Control *ND- Not Detected *NA- Not Applicable

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