



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

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

Date: 20/04/2021

Doc ID: COA/TP/USPK461-P

Product: Trueprep[®] AUTO Universal Cartridge Based Sample Prep Kit	
Trueprep[®] AUTO Universal Cartridge Based Sample Prep Kit	Lot No.: USPK461-P Mfg Date: 2021-04 Exp Date: 2023-03
	A.R. No.: B-USPK-461-P
Pack size: 5, 25, 50 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 Cartridge Based Sample prep kit)	(Present (P)/Not Present (NP))	
1	Universal Reagent Pack	Present	Present
2	Universal Cartridge Pack	Present	Present
3	Disposable Transfer Pipette (3 ml)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab[®] micro PCR Analyzers

Sr. No	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
1	Negative MTB	ND	30.33
2	Positive MTB	27.86	30.0
3	Positive MTB	27.8	27.5
4	Negative HBV	ND	30.75
5	Positive HBV	29.5	30.2
6	Positive HIV	29.0	28.8
7	Negative HCV	ND	30.0

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0



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Performance on Truelab® micro PCR Analyzers			
8	Positive HCV	29.73	29.14
9	Negative COVID-19	ND	22.6
10	Positive COVID-19	28.5	26.8

*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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