



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

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

Date: 16/04/2021

Doc ID: COA/TP/USPK459-P

Product: Trueprep[®] AUTO Universal Cartridge Based Sample Prep Kit	
Trueprep[®] AUTO Universal Cartridge Based Sample Prep Kit	Lot No.: USPK459-P Mfg Date: 2021-03 Exp Date: 2023-02
	A.R. No.: B-USPK-459-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	27.6
2	Positive MTB	28.0	28.33
3	Positive MTB	28.0	27.33
4	Negative HBV	ND	31.0
5	Positive HBV	30.43	30.43
6	Positive HBV	29.22	28.33
7	Negative HIV	ND	30.17

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab[®] micro PCR Analyzers			
8	Positive HIV	30.0	28.17
9	Negative HCV	ND	28.83
10	Positive HCV	29.6	29.33

*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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