



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

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

Date: 07/05/2021

Doc ID: COA/TP/USPK465-P

Product: Trueprep[®] AUTO Universal Cartridge Based Sample Prep Kit	
Trueprep[®] AUTO Universal Cartridge Based Sample Prep Kit	Lot No.: USPK465-P Mfg Date: 2021-04 Exp Date: 2023-03
	A.R. No.: B-USPK-465-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	28.0
2	Positive MTB	27.2	30.2
3	Positive MTB	27.33	29.0
4	Negative HBV	ND	30.2
5	Positive HBV	29.25	30.2
6	Positive HCV	30.1	30.13

*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

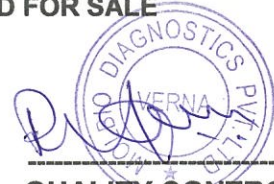
7	Positive HIV	29.0	29.14
8	Negative COVID-19	ND	23.0

*Ct- Cycle threshold

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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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