



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

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

Date: 24/06/2021

Doc ID: COATP/VUCPK143-P

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep® AUTO Universal Cartridge Based Sample Prep Kit	Lot No.: VUCPK143-P Mfg Date: 2021-05 Exp Date: 2023-04
	A.R. No.: B-VUCPK-143-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	27.75
2	Positive MTB	27.4	27.8
3	Positive HBV	28.0	29.8
4	Negative HBV	ND	30.2
5	Positive HCV	29.89	30.6
6	Positive HIV	31.4	28.4
7	Negative HBV	ND	29.17

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

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab® micro PCR Analyzers

8	Negative COVID-19	ND	23.4
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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


R. Sharma

QUALITY CONTROL
Name: Dr. Praveen Kumar
for Designation: QC Head

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