



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

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

Date: 07/07/2021

Doc ID: COA/TP/VUCPK145-PL

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep® AUTO Universal Cartridge Based Sample Prep Kit	Lot No.:VUCPK145-PL Mfg Date: 2021-06 Exp Date: 2023-05
	A.R. No.: B-VUCPK-145-PL
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	29.17
2	Positive MTB	30.4	27.14
3	Positive MTB	30.29	26.6
4	Negative HBV	ND	29.75
5	Negative COVID-19	ND	24.17
6	Negative COVID-19	ND	20.5
7	Negative DENGUE	ND	28.67
8	Positive HCV	29.23	28.67

*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			
9	Positive HCV	28.46	29.0
10	Positive HIV	32.2	30.6
11	Negative MTB Plus	ND	28.17
12	Positive MTB Plus	29.0	30.33

*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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