



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 06/05/2021

Doc ID: COA/TP/VUCPK121-P

Product: Trueprep[®] AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep[®] AUTO v2 Universal Cartridge Based Sample Prep Kit	Lot No.: VUCPK121-P Mfg Date: 2021-03 Exp Date: 2023-02
	A.R. No.: B-VUCPK-121-P
Pack size: 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 v2 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	28.57
2	Positive MTB	27.8	26.4
3	Positive MTB	27.8	29.14
4	Negative Dengue	ND	30.67
5	Negative HIV	ND	30.0

*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			
6	Positive HIV	29.67	28.6
7	Negative HCV	ND	31.0
8	Positive HCV	30.15	30.0
9	Negative COVID-19	ND	22.17
10	Negative COVID-19	ND	24.33

*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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