



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

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

Date: 01/06/2021

Doc ID: COA/TP/VUCPK135-P

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep® AUTO Universal Cartridge Based Sample Prep Kit	Lot No.: VUCPK135-P Mfg Date: 2021-05 Exp Date: 2023-04
	A.R. No.: B-VUCPK-135-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		29.0	
2	Positive MTB	27.5		30.0	
3	Positive MTB	27.64		30.64	
4	Negative Dengue	ND		27.33	
5	Positive HBV	28.63		30.5	

*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	30.5	29.29
7	Positive HCV	29.67	30.0
8	Negative COVID-19	ND	25.0
9	Negative COVID-19	ND	24.0

*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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