



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

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

Date: 01/12/2021

Doc ID: COA/TP/VUCPK164-PLM

Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: VUCPK164-PLM	Mfg. Date: 2021-10	Exp. Date: 2023-09
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-VUCPK-164-PLM

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 Dengue	ND	28.5
2	Negative MTB	ND	27.5
3	Negative COVID-19	ND	27.6
4	Negative COVID-19	ND	27.75
5	Positive HBV	28.17	27.75
6	Positive HBV	28.0	30.0

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

Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
7	Positive HCV	30.25	26.8
8	Positive HIV	29.43	26.43
9	Positive MTB	28.0	27.4
10	Positive MTB	27.0	27.0

*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.



Praveen

QUALITY CONTROL

Name: Dr. Praveen Kumar

for Designation: QC Head

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