



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 03/05/2021

Doc ID: COA/TP/VUCPK118-P

Product: Trueprep <sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep <sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit	Lot No.: VUCPK118-P Mfg Date: 2021-03 Exp Date: 2023-02
	A.R. No.: B-VUCPK-118-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 <sup>®</sup> 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 <sup>®</sup> 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	28.5
2	Negative HBV	ND	27.6
3	Positive HCV	31.0	30.5
4	Positive HIV	29.17	27.17
5	Negative HIV	ND	30.0

\*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

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab <sup>®</sup> micro PCR Analyzers			
6	Negative HIV	ND	30.0
7	Negative HCV	ND	30.5
8	Negative COVID-19	ND	20.6
9	Positive COVID-19	ND	23.5

\*Ct- Cycle threshold

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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

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

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