



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

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

Date: 17/12/2021

Doc ID: COA/TP/VUCPK228-PM

<b>Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: VUCPK228-PM</b>	<b>Mfg. Date: 2021-10</b>	<b>Exp. Date: 2023-09</b>
<b>Pack size: 50T, 5T</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-VUCPK-228-PM</b>

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
<b>A</b>	<b>Contents in the carton (Trueprep® AUTO v2 Universal Cartridge Based Sample prep kit)</b>	<b>(Present (P)/Not Present (NP))</b>	
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	29.0
2	Negative MTB	ND	27.57
3	Negative COVID-19	ND	27.8
4	Negative COVID-19	ND	27.75
5	Positive HBV	28.4	27.14
6	Positive HBV	29.13	29.0

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

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	27.89	26.29
8	Positive HIV	28.33	27.5
9	Positive MTB	29.17	29.0
10	Positive MTB	28.33	27.8

\*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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