



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

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

Date: 20/12/2021

Doc ID: COA/TP/VUCPK229-PLM

<b>Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: VUCPK229-PLM</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-229-PLM</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 HCV	ND	29.0
2	Negative Dengue	ND	29.13
3	Negative COVID-19	ND	28.0
4	Negative MTB	ND	28.14
5	Positive HBV	28.43	30.2
6	Positive HBV	28.17	29.17

**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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<b>Performance on Truelab® micro PCR Analyzers</b>			
<b>Sr. No.</b>	<b>Sample Negative/Positive</b>	<b>Negative: Test- ND</b>	<b>IC- Detected</b>
		<b>Positive: Test- Detected</b>	<b>IC- Detected</b>
		<b>Test (Ct)</b>	<b>IC (Ct)</b>
7	Positive HCV	29.31	27.8
8	Positive HIV	28.5	26.63
9	Positive MTB	27.43	28.6
10	Positive MTB	27.33	28.67

\*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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