



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

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

Date: 19/04/2021

Doc ID: COA/TP/USPK460-P

<b>Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit</b>	
<b>Trueprep® AUTO Universal Cartridge Based Sample Prep Kit</b>	<b>Lot No.: USPK460-P Mfg Date: 2021-03 Exp Date: 2023-02</b>
	<b>A.R. No.: B-USPK-460-P</b>
<b>Pack size: 5, 25, 50 TESTS</b>	<b>Storage: 2°C to 40°C</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 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 MTB	ND	29.5
2	Positive MTB	28.8	28.43
3	Positive MTB	28.5	27.14
4	Negative HBV	ND	30.0
5	Negative HBV	ND	28.17
6	Positive HBV	30.2	30.8
7	Positive HIV	29.4	29.29

\*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			
8	Negative HCV	ND	30.25
9	Positive HCV	29.08	30.67
10	Negative COVID-19	ND	22.0

\*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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