



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

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

Date: 09/12/2021

Doc ID: COA/TP/USPK562-PLM

<b>Product: Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: USP562-PLM</b>	<b>Mfg. Date: 2021-11</b>	<b>Exp. Date: 2023-10</b>
<b>Pack size: 5, 25, 50 TESTS</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-USPK-562-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<sup>®</sup> 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

<b>Performance on Truelab<sup>®</sup> micro PCR Analyzers</b>			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		<b>Test (Ct)</b>	<b>IC (Ct)</b>
1	Negative HBV	ND	30.33
2	Negative MTB	ND	28.0
3	Negative COVID-19	ND	26.33
4	Negative COVID-19	ND	26.14
5	Negative HCV	ND	27.5

## 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			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
6	Positive MTB	29.0	27.6
7	Positive MTB	28.33	29.33
8	Positive HBV	27.75	30.8
9	Positive HCV	30.21	28.0
10	Positive HIV	29.75	27.63

\*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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