



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

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

**Date: 23/09/2021**

**Doc ID: COA/TP/USPK482-PL**

<b>Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: USPK482-PL</b>	<b>Mfg Date: 2021-05</b>	<b>Exp Date: 2023-04</b>
<b>Pack size: 5, 25, 50 TESTS</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-USPK-482-PL</b>

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

<b>Sr. No.</b>	<b>Components in each kit</b>	<b>Specification</b>	<b>Observation</b>
<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

<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>
1	Negative HCV	ND	29
2	Positive HBV	28.56	30.14
3	Positive HBV	28.38	29.36
4	Positive HCV	29.5	30.67
5	Positive HCV	29.15	30.6
6	Negative MTB	ND	29.5
7	Positive MTB	27.33	29

**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



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

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

**Date:** 23/09/2021

**Doc ID:** COA/TP/USPK482-PL

<b>Product:</b> Trueprep® AUTO Universal Cartridge Based Sample Prep Kit		
<b>Lot No.:</b> USPK482-PL	<b>Mfg Date:</b> 2021-05	<b>Exp Date:</b> 2023-04
<b>Pack size:</b> 5, 25, 50 TESTS	<b>Storage:</b> 2°C to 40°C	<b>A.R. No.:</b> B-USPK-482-PL

<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>
8	Positive HIV	30	31
9	Negative COVID-19	ND	26.5
10	Positive COVID-19	27.8	22.6

\*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

*for* **Designation:** QC Head

**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