



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

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

Date: 29/09/2021

Doc ID: COA/TP/USPK483-PL

<b>Product: Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit</b>		
<b>Lot No.: USPK483-PL</b>	<b>Mfg Date: 2021-07</b>	<b>Exp Date: 2023-06</b>
<b>Pack size: 5, 25, 50 TESTS</b>	<b>Storage: 2°C to 40°C</b>	<b>A.R. No.: B-USPK-483-PL</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

**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)
1	Negative DENGUE	ND	29.29
2	Negative HIV	ND	27.5
3	Positive HBV	29.0	29.4
4	Positive HCV	27.9	28.0
5	Positive HCV	28.7	28.33
6	Negative MTB	ND	29.17
7	Positive MTB	28.17	28.8

**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: 29/09/2021

Doc ID: COA/TP/USPK483-PL

Product: Trueprep<sup>®</sup> AUTO Universal Cartridge Based Sample Prep Kit

Lot No.: USPK483-PL

Mfg Date: 2021-07

Exp Date: 2023-06

Pack size: 5, 25, 50 TESTS

Storage: 2°C to 40°C

A.R. No.: B-USPK-483-PL

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)
8	Positive MTB	28.0	29.14
9	Negative COVID-19	ND	25.5
10	Positive HIV	30.0	29.17

\*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