



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

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

Date:30/08/2021

Doc ID:COA/TP/VUCPK156-PL

Product: Trueprep <sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: VUCPK156-PL	Mfg Date: 2021-06	Exp Date: 2023-05
Pack size: 50T ,5T	Storage: 2°C to 40°C	A.R. No.: B-VUCPK-156-PL

**5PRECAUTION:** 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 MTB	ND	27.5
2	Positive MTB	28.33	28.13
3	Positive MTB	27.83	29.0
4	Negative MTB Plus	ND	28.17
5	Positive MTB Plus	29.6	29.33
6	Positive MTB Plus	28.0	29.0
7	Positive HBV	29.1	28.75
8	Negative HBV	ND	30.17
9	Positive HIV	29.0	30.8

\*Ct- Cycle threshold

\*IC- Internal Control

\*ND- Not Detected

## Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0



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Performance on Truelab <sup>®</sup> micro PCR Analyzers			
10	Positive HIV	29.57	30.6
11	Positive HCV	29.64	29.75
12	Negative COVID-19	ND	25.0
13	Negative COVID-19	ND	25.33

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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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