



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

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

Date: 29/10/2021

Doc ID: COA/TP/VUCPK159-PL

Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: VUCPK159-PL	Mfg. Date: 2021-10	Exp. Date: 2023-09
Pack size: 50T , 5T	Storage: 2°C to 40°C	A.R. No.: B-VUCPK-159-PL

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

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (Trueprep® AUTO Universal Cartridge Based Sample prep kit)	(Present (P)/Not Present (NP))	
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 DENGUE	ND	27.25
2	Negative MTB	ND	26.29
3	Negative COVID-19	ND	25.33
4	Negative COVID-19	ND	25.0
5	Positive HBV	29.0	27.75
6	Positive HBV	28.5	27.13

## Molbio Diagnostics Private Limited

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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)
7	Positive HCV	30.58	27.5
8	Positive HIV	29.33	27.8
9	Positive MTB	28.6	27.6
10	Positive MTB	28.0	27.8

\*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