

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

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

Date: 15/05/2021

Doc ID: COA/TP/VUCPK128-P

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit

Trueprep® AUTO Universal

Lot No.: VUCPK128-P Mfg Date: 2021-04 Exp Date: 2023-03

**Cartridge Based** 

A.R. No.: VUCPK128-P

Sample Prep Kit

Pack size: 5, 25, 50 TESTS

Storage: 2°C to 40°C

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)/No	t 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: Test- ND Positive: Test- Detected		IC- Detected IC- Detected		
		Test (Ct)	IC (Ct)		
1	Positive MTB	29.37	28.47		
2	Positive MTB	30.0	27.67		
3	Negative Dengue	ND	28.0		
4	Negative Dengue	ND	27.6		
5	Positive HCV	30.6	30.5		

<sup>\*</sup>Ct- Cycle threshold

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<sup>\*</sup>IC- Internal Control

<sup>\*</sup>ND- Not Detected



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Trueprep® AUTO Universal	Lot No.: VUCPK128-P Mfg Date: 2021-04 Exp Date: 202	3-03
Cartridge Based Sample Prep Kit	A.R. No.: VUCPK128-P	
Pack size: 5, 25, 50 TESTS	Storage: 2°C to 40°C	

Performance on Truelab® micro PCR Analyzers					
6	Negative COVID-19	ND	23.17		
7	Negative COVID-19	ND	22.75		
8	Positive HIV	30.29	30.33		

\*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 SALEOS

QUALITY CONTROL Name: Dr. Praveen Kumar Designation: QC Head

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