



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

Mfg.Lic. No.: MFG/IVD/2021/000064

Date: 22/01/2022

Doc ID: COA/TP/001VUCPK-PLM

Product: Trueprep[®] AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: 001VUCPK-PLM	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-001-VUCPK-PLM

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 v2 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 HCV	ND	28.31
2	Negative HBV	ND	29.8
3	Negative COVID-19	ND	23
4	Negative MTB	ND	30
5	Positive HBV	26.43	30
6	Positive HCV	29.14	29.57



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

Mfg.Lic. No.: MFG/IVD/2021/000064

Date: 22/01/2022

Doc ID: COA/TP/001VUCPK-PLM

Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: 001VUCPK-PLM	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-001-VUCPK-PLM

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)
7	Positive HIV	29	28.14
8	Positive HIV	29.2	28.17
9	Positive MTB	27.14	30.33
10	Positive COVID-19	20	20.14

*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
for