



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

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

Date: 30/06/2022

Doc ID: COA/TP/007VUCPK-PLM

Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: 007VUCPK-PLM	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-007-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 graduated (3 ml)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab® Real Time micro PCR Analyzers

Sr. No.	Sample Negative/Positive	Negative: Test- ND		IC- Detected
		Positive: Test- Detected		IC- Detected
		Test 1 (Ct)	Test 2 (Ct)	IC (Ct)
1	Negative HBV	ND	NA	27.83
2	Negative HCV	ND	NA	28
3	Negative MTB	ND	NA	29
4	Positive HBV	29.29	NA	27.2
5	Positive HBV	29.14	NA	27.5
6	Positive HCV	30.88	NA	27.17

Molbio Diagnostics Private Limited

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Performance on Truelab [®] Real Time micro PCR Analyzers				
Sr. No.	Sample Negative/Positive	Negative: Test- ND		IC- Detected
		Positive: Test- Detected		IC- Detected
		Test 1 (Ct)	Test 2 (Ct)	IC (Ct)
7	Positive HCV	30.23	NA	27.25
8	Positive HIV	29.17	NA	27.17
9	Positive MTB	31	NA	27.33
10	Positive MTB	31.4	NA	29.5

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

*NA- Not Applicable

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