



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

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

Date: 08/07/2022

Doc ID: COA/TP/008VUCPK-PLM

Product: Trueprep[®] AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: 008VUCPK-PLM	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-008-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 (Ct)	IC (Ct)
1	Negative HCV	ND	28.57
2	Negative HIV	ND	28.2
3	Negative HBV	ND	28.57
4	Negative MTB	ND	28.25
5	Positive HBV	30.43	27.5
6	Positive HBV	30.2	27.4

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 (Ct)	IC (Ct)
7	Positive HIV	29.6	27.38
8	Positive HIV	29.5	27.67
9	Positive HCV	30.89	27.29
10	Positive HCV	30	27.83
11	Positive MTB	32	29.33
12	Positive MTB	31.07	28.83

*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