



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

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

Date: 22/07/2022

Doc ID: COA/TP/013USPK-PLM

Product: Trueprep[®] AUTO Universal Cartridge Based Sample Prep Kit		
Lot No.: 013USPK-PLM	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 50T, 25T, 5T	Storage: 2°C to 40°C	A.R. No.: B-013-USPK-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 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 Analyzer			
Sr. No.	Sample Negative/Positive	Negative: Test- ND	IC- Detected
		Positive: Test- Detected	IC- Detected
		Test (Ct)	IC (Ct)
1	Negative HBV	ND	29.27
2	Negative HCV	ND	28.27
3	Negative HIV	ND	28.75
4	Negative MTB	ND	29.33
5	Positive HBV	29.56	29.75
6	Positive HBV	29.88	29.29

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 HCV	30.7		29.6	
8	Positive HCV	30.89		28.13	
9	Positive HIV	29.67		29	
10	Positive HIV	29		29.67	
11	Positive MTB	30		29	
12	Positive MTB	30.63		28.6	

*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