



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

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

Date: 05/07/2022

Doc ID: COA/TP/010USPK-PLM

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit		
Lot No.: 010USPK-PLM	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 5, 25, 50 TESTS	Storage: 2°C to 40°C	A.R. No.: B-010-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	27.8
2	Negative HCV	ND	28.5
3	Negative MTB	ND	29
4	Positive HBV	30.18	27.63
5	Positive HBV	30.5	28.75

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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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)
6	Positive HCV	30.45	28.1
7	Positive HCV	30.36	28
8	Positive HIV	31	29.4
9	Positive MTB	30.83	30
10	Positive MTB	31.33	29.6

*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.


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Name: Dr. Praveen Kumar
Designation: QC Head

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