



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

Mfg.Lic. No.: MFG/IVD/2019/000003

Date: 05/10/2021

Doc ID: COA/TP/USPK484-PL

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit		
Lot No.: USPK484-PL	Mfg Date: 2021-07	Exp Date: 2023-06
Pack size: 5, 25, 50 TESTS	Storage: 2°C to 40°C	A.R. No.: B-USPK-484-PL

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 (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 HBV	ND	29.5
2	Negative MTB	ND	30.17
3	Positive MTB	28.8	28.8
4	Positive MTB	28.33	28.8
5	Positive HBV	29.0	29.0
6	Positive HBV	29.8	30.56

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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 HCV	31.78	28.5
8	Positive HIV	29.33	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