



MOLBIO DIAGNOSTICS PVT. LTD.
An ISO 9001:2015 & ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 29/01/2020

Product: Trueprep® AUTO Universal Cartridge Based Sample prep kit	
Trueprep® AUTO Universal Cartridge Based Sample prep kit	Lot No.: USPK260 Mfg Date: 2019-10 Exp Date: 2021-09 A.R. No.: B-USPK-260
Pack size: 5, 25 TESTS	Storage: 2°C to 40°C

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 HCV	ND	29.89
2	Negative HCV	ND	29.5
3	Positive HCV	29.64	29.13
4	Positive HCV	28.45	27.5
5	Positive HCV	29.3	29.0
6	Positive HCV	29.8	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

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Designation: QC Head

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