



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

CERTIFICATE OF ANALYSIS

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

Date: 27/01/2020

Product: Trueprep® AUTO Universal Cartridge Based Sample prep kit	
Trueprep® AUTO Universal Cartridge Based Sample prep kit	Lot No.: USPK258 Mfg Date: 2019-10 Exp Date: 2021-09
	A.R. No.: B-USPK-258
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	28.8
2	Negative HCV	ND	30.33
3	Positive HCV	28.5	28.17
4	Positive HCV	29.55	29
5	Positive HCV	29.42	29
6	Positive HCV	30.5	28.33

*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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