



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

CERTIFICATE OF ANALYSIS

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

Date: 22/02/2020

Product: Trueprep[®] AUTO Universal Cartridge Based Sample prep kit

Trueprep[®] AUTO Universal
Cartridge Based
Sample prep kit

Lot No.: USPK273 Mfg Date: 2020-01 Exp Date: 2021-12

A.R. No.: B-USPK-273

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	30
2	Negative HCV	ND	30.4
3	Positive HCV	29.29	28.5
4	Positive HCV	28.58	28.14
5	Positive HCV	28.23	28.33
6	Positive HCV	30.55	29

*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

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