



MOLBIO DIAGNOSTICS PVT. LTD.
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CERTIFICATE OF ANALYSIS

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

Date: 07/02/2020

Product: Trueprep [®] AUTO Universal Cartridge Based Sample prep kit	
Trueprep [®] AUTO Universal Cartridge Based Sample prep kit	Lot No.: USP265 Mfg Date: 2020-01 Exp Date: 2021-12 A.R. No.: B-USPK-265
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 MTB	ND	28.8
2	Positive MTB	33.4	28.2
3	Negative HBV	ND	29.75
4	Positive HBV	27.6	31
5	Positive HCV	29.55	28.13
6	Positive HIV	27.8	26.14

*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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