



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

CERTIFICATE OF ANALYSIS

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

Date: 13/03/2020

Product: Trueprep [®] AUTO Universal Cartridge Based Sample prep kit	
Trueprep [®] AUTO Universal Cartridge Based Sample prep kit	Lot No.: USPK278 Mfg Date: 2020-02 Exp Date: 2022-01
	A.R. No.: B-USPK-278
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	
		Test (Ct)	IC (Ct)
1	Negative MTB	ND	30.8
2	Negative MTB	ND	30
3	Negative HBV	ND	30.67
4	Positive HBV	28.5	29.5
5	Positive HCV	28.33	30
6	Positive HIV	29	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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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0