



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date: 16/12/2021

Doc ID: COA/TP/USPK563-PLM

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit		
Lot No.: USP563-PLM	Mfg. Date: 2021-12	Exp. Date: 2023-11
Pack size: 5, 25, 50 TESTS	Storage: 2°C to 40°C	A.R. No.: B-USPK-563-PLM

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 HBV	ND	29.4
2	Negative MTB	ND	27.57
3	Negative COVID-19	ND	26.75
4	Negative DENGUE	ND	30.0
5	Positive MTB	28.6	28.14

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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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)
6	Positive MTB	27.5	26.2
7	Positive HBV	30.33	30.0
8	Positive HBV	28.75	29.67
9	Positive HCV	30.14	29.0
10	Positive HIV	28.17	26.0

*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