



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

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

Date: 27/01/2022

Doc ID: COA/TP/USPK565-PLM

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit		
Lot No.: USPK565-PLM	Mfg. Date: 2022-01	Exp. Date: 2023-12
Pack size: 5, 25, 50 TESTS	Storage: 2°C to 40°C	A.R. No.: B-USPK-565-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 HIV	ND	30.14
2	Negative COVID-19	ND	26.6
3	Negative MTB	ND	28.14
4	Positive MTB	29.0	29.43
5	Positive MTB	28.19	28.31

Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab® micro PCR Analyzers

Sr. No.	Sample Negative/Positive	Negative: Test- ND Positive: Test- Detected	IC- Detected IC- Detected
		Test (Ct)	IC (Ct)
6	Positive HBV	28.0	29.6
7	Positive HBV	27.8	28.0
8	Positive HCV	30.83	29
9	Positive HIV	29.67	28.17
10	Positive COVID-19	30.13	25.67

*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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