



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

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

Date:31/07/2021

Doc ID:COA/TP/VUCPK150-PL

Product: Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: VUCPK150-PL	Mfg Date: 2021-06	Exp Date: 2023-05
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-VUCPK-150-PL

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	28.14	27.67
3	Positive MTB	28.17	28.8
4	Negative MTB Plus	ND	29.5
5	Positive MTB Plus	28.0	30.0
6	Positive MTB Plus	27.0	28.75
7	Negative HBV	ND	30.33
8	Negative COVID-19	ND	20.6
9	Positive HBV	28.33	28.43

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab® micro PCR Analyzers			
10	Positive HIV	30.13	28.8
11	Positive HIV	30.0	29.0
12	Positive HCV	30.5	30.75
13	Positive HCV	30.78	28.0

*Ct- Cycle threshold

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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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