



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

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

Date: 15/02/2022

Doc ID: COA/TP/VUCPK234-PLM

Product: Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: VUCPK234-PLM	Mfg. Date: 2022-02	Exp. Date: 2024-01
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-VUCPK-234-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 v2 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 Graduated)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab [®] Real Time micro PCR Analyzers						
Sr. No	Control	Specification (Ct Values)		Test Lot (Ct Values)		
1	Specificity Tests	Test	IC	Test 1	Test 2	IC
Negative Control						
1	Negative HCV	ND	Control should be detected	ND	NA	30.0
2	Negative COVID-19			E.gene:ND	Orf1A:ND	26.33
3	Negative Sputum			ND	NA	28.33
Positive Control						
1	Positive HBV	Test and Control should be detected		27.5	NA	30.13
2	Positive HIV	Test and Control should be detected		29.57	NA	29.5
3	Positive HIV	Test and Control should be detected		29.25	NA	28.29
4	Positive HCV	Test and Control should be detected		27.0	NA	28.2
5	Positive HCV	Test and Control should be detected		26.55	NA	27.8

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

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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6	Positive COVID-19	Test and Control should be detected	E.gene:26.5	Orf1A:26.6	23.13
7	Positive Sputum	Test and Control should be detected	28.33	NA	27.67

*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

for Designation: QC Head

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