



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

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

Date: 29/10/2021

Doc ID: COA/TP/VUCPK157-PL

Product: Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: VUCPK157-PL	Mfg. Date: 2021-06	Exp. Date: 2023-05
Pack size: 50T , 5T	Storage: 2°C to 40°C	A.R. No.: B-VUCPK-157-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 DENGUE	ND	30.25
2	Negative MTB	ND	30.14
3	Negative COVID-19	ND	26.0
4	Positive HBV	29.17	29.8
5	Positive HCV	33.03	29.8
6	Positive HCV	32.14	30.5

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

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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)
7	Positive HIV	30.33	30.33
8	Positive HIV	29.2	29.5
9	Positive MTB	27.17	29.0
10	Positive MTB	26.8	28.6

*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



for **QUALITY CONTROL**
Name: Dr. Praveen Kumar
Designation: QC Head