



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

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

Date:24/07/2021

Doc ID:COA/TP/VUCPK149-PL

Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit		
Lot No.: VUCPK149-PL	Mfg Date: 2021-06	Exp Date: 2023-05
Pack size: 50T, 5T	Storage: 2°C to 40°C	A.R. No.: B-VUCPK-149-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	28.0
2	Positive MTB	26.6	27.43
3	Positive MTB	28.14	28.13
4	Negative MTB Plus	ND	30.0
5	Positive MTB Plus	27.75	26.83
6	Positive MTB Plus	27.33	30.0
7	Negative HBV	ND	30.0
8	Negative Dengue	ND	27.0
9	Positive HBV	30.6	30.33

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

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			
10	Positive HIV	30.0	29.75
11	Positive HIV	31.33	30.2
12	Positive HCV	30.8	28.75

*Ct- Cycle threshold

*IC- Internal Control

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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


VERNA
MOLBIO DIAGNOSTICS PVT. LTD.
QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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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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