



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

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

Date: 10/07/2021

Doc ID: COA/TP/VUCPK146-PL

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep® AUTO Universal Cartridge Based Sample Prep Kit	Lot No.:VUCPK146-PL Mfg Date: 2021-06 Exp Date: 2023-05 A.R. No.: B-VUCPK-146-PL
Pack size: 5, 25, 50 TESTS	Storage: 2°C to 40°C

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	30.33
2	Positive MTB	32.14	29.6
3	Positive MTB	31.4	29.33
4	Negative HBV	ND	26.8
5	Negative COVID-19	ND	24.6
6	Negative COVID-19	ND	26.5
7	Negative HCV	ND	30.17
8	Positive HCV	29.86	29.8

*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



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

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

Date: 10/07/2021

Doc ID: COA/TP/VUCPK146-PL

Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit	
Trueprep® AUTO Universal Cartridge Based Sample Prep Kit	Lot No.:VUCPK146-PL Mfg Date: 2021-06 Exp Date: 2023-05
	A.R. No.: B-VUCPK-146-PL
Pack size: 5, 25, 50 TESTS	Storage: 2°C to 40°C

Performance on Truelab® micro PCR Analyzers			
9	Positive HBV	28.8	28.0
10	Positive HIV	32.83	29.4
11	Negative MTB PLUS	ND	29.13
12	Positive MTB PLUS	32	29
13	Positive MTB PLUS	31.8	28.8

*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

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