



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 21/06/2024

Doc ID: COA/TP/121VUCPK/50T

<b>Product Name</b>	Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit
<b>Generic Name</b>	Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2
<b>Lot No.</b>	121VUCPK
<b>Mfg. Date</b>	2024-03
<b>Exp. Date</b>	2026-02
<b>Pack Size</b>	50T
<b>Storage condition</b>	2°C to 40°C

**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	<b>Contents in the carton (Trueprep® AUTO v2 Universal Cartridge Based Sample prep kit)</b>	<b>(Present (P)/Not Present (NP))</b>	
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

**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



Performance on Truelab® Real Time micro PCR Analyzer						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1 (Average)	Test 2 (Average)	IC (Average)
<b>Negative Control</b>						
1	Negative MTB	ND	Control should be detected	ND	NA	28.06
2	Negative HBV	ND		ND	NA	26.69
3	Negative HCV	ND		ND	NA	26.33
4	Negative HIV-1	ND		ND	NA	26.41
<b>Positive Control</b>						
1	Positive MTB	Test and Control should be detected		31.21	NA	28.46
2	Positive MTB Plus	Test and Control should be detected		30.78	NA	26.23
3	Positive HCV	Test and Control should be detected		31.73	NA	26.23
<b>Non Template Control Test for COVID-19</b>						
1	NTC	Test 1, Test 2 and Control should not be detected		ND	ND	ND

\*Ct-Cycle Threshold \*IC- Internal Control \*ND- Not Detected \*NA- Not Applicable \*NTC- Non Template Control

**Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.**

  
  
**Name: Dr. Praveen Kumar MK**  
**Department: Quality Control**  
**Designation: QC Head**