



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 13/02/2024

Doc ID: COA/TP/037USPKL

Product Name	Trueprep® AUTO Universal Cartridge Based Sample Prep Kit
Generic Name	Sample preparation kit for nucleic acid extraction on Trueprep® AUTO
Lot No.	037USPKL
Mfg. Date	2024-01
Exp. Date	2025-12
Pack Size	50T
Storage condition	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 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)	
	Specificity Tests	Test	IC	Test 1 (Average)	Test 2 (Average)	IC (Average)
Negative Control						
1	Negative HBV	ND	Control should be detected	ND	NA	26.23
2	Negative HCV	ND		ND	NA	27.66
3	Negative HIV-1	ND		ND	NA	27.23
4	Negative MTB	ND		ND	NA	27.28
Positive Control						
1	Positive MTB	Test and Control should be detected		30.78	NA	28.21
2	Positive HCV	Test and Control should be detected		30.74	NA	27.44
Non Template Control Test for COVID-19						
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  
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**Designation:** QC Head