

ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

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

Date: 21/10/2021

Doc ID: COA/TP/USPK489-PL

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit

Lot No.: USPK489-PL Mfg. Date: 2021-07 Exp. Date: 2023-06

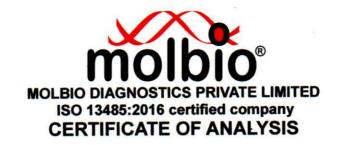
Pack size: 5, 25, 50 TESTS Storage: 2°C to 40°C A.R. No.: B-USPK-489-PL

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

Sr. No.	Components in each kit	Specification	Observation	
Α	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	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 Positive: Test- Detected	IC- Detected IC- Detected		
		Test (Ct)	IC (Ct)		
1	Negative HBV	ND	28.67		
2	Negative MTB	ND	29.67		
3	Negative COVID-19	ND	26.8		
4	Negative COVID-19	ND	26.2		
5	Negative DENGUE	ND	29.25		
6	Positive MTB	29.88	28.86		

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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Performance on Truelab® micro PCR Analyzers						
Sr. No.	Sample Negative/Positive	Negative: Test- ND Positive: Test- Detected	IC- Detected IC- Detected			
-		Test (Ct)	IC (Ct)			
. 7	Positive MTB	29	28.75			
8	Positive HBV	28.8	30.43			
9	Positive HCV	32.7	29.4			
10	Positive HIV	29.17	28.33			

<sup>\*</sup>Ct- Cycle threshold

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

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<sup>\*</sup>IC- Internal Control

<sup>\*</sup>ND- Not Detected