



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 22/02/2021

PRODUCT: Trueprep® AUTO MTB Sample Pre-treatment Pack	
Trueprep® AUTO MTB Sample Pre-treatment Pack	Lot No.: MSPT089 Mfg Date: 2021-01 Exp Date: 2022-12
	A.R. No.: B-MSPT-089
Pack size: 50T, 20T, 5T	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 (MTB Sample Pre-treatment Pack)	(Present (P)/Not Present (NP))	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1ml)	Present	Present

Performance on Truelab® Real Time micro PCR Analyzers					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
Negative Control					
1	Sample 1	ND	Control should be detected	ND	30.0
2	Sample 2	ND	Control should be detected	ND	29.0
3	Sample 3	ND	Control should be detected	ND	29.0
Positive Control					
1	Sample 1	Test and Control should be detected		27.0	28.14
2	Sample 2	Test and Control should be detected		27.33	27.33
3	Sample 3	Test and Control should be detected		27.17	30.33

\*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



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Mfg.Lic. No. : MFG/IVD/2020/000119

Date: 22/02/2021

<b>PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack</b>	
<b>Trueprep® AUTO Universal Sample Pre-treatment Pack</b>	<b>Lot No.: USPT143 Mfg Date: 2021-01 Exp Date: 2022-12</b>
	<b>A.R. No.: B-USPT-143a</b>
<b>Pack size : 50T, 20T, 5T</b>	<b>STORAGE : 2°C to 40°C</b>

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

Sr. No.	Components in each kit	Specification	Observation
<b>A</b>	<b>Contents in the carton (Trueprep® AUTO Universal Sample Pre- treatment Pack)(Present (P)/Not Present (NP))</b>	<b>(Present (P)/ Not Present (NP))</b>	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1ml)	Present	Present

<b>Performance on Truelab® micro PCR Analyzers</b>					
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
1	<b>Specificity Tests</b>	<b>Test</b>	<b>IC</b>	<b>Test</b>	<b>IC</b>
<b>Negative Control</b>					
1	Neg HBV	ND	Control should be detected	ND	28.29
2	Neg HIV	ND	Control should be detected	ND	29.75
3	Neg COVID-19	ND	Control should be detected	ND	24.33
<b>Positive Control</b>					
1	Pos HBV	Test and Control should be detected		28.33	28.0
2	Pos HCV	Test and Control should be detected		29.7	30.33
3	Pos COVID-19	Test and Control should be detected		27.75	24.4

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Date: 20/02/2021

PRODUCT : Trueprep® AUTO Universal Sample Pre-treatment Pack	
Trueprep® AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT142 Mfg Date: 2021-01 Exp Date: 2022-12
	A.R. No.: B-USPT-142b
Pack size : 50T, 20T, 5T	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 Sample Pre- treatment Pack)(Present (P)/Not Present (NP))	(Present (P)/ Not Present (NP))	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1ml)	Present	Present

Performance on Truelab® micro PCR Analyzers					
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
Negative Control					
1	Neg HBV	ND	Control should be detected	ND	27.2
2	Neg HIV	ND	Control should be detected	ND	30.75
3	Neg COVID-19	ND	Control should be detected	ND	22.2
Positive Control					
1	Pos HBV	Test and Control should be detected		29.8	28.67
2	Pos HCV	Test and Control should be detected		28.07	27.2
3	Pos COVID-19	Test and Control should be detected		29.13	21.0

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

Date: 20/02/2021

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit	
Trueprep® AUTO Universal Cartridge Based Sample Prep Kit	Lot No.: USPK442-P Mfg Date: 2020-09 Exp Date: 2022-08
	A.R. No.: B-USPK-442-P
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 Positive: Test- Detected	IC- Detected IC- Detected
		Test (Ct)	IC (Ct)
1	Negative MTB	ND	29.5
2	Positive MTB	27.33	28.8
3	Negative HBV	ND	29.0
4	Positive HBV	30.13	27.2
5	Negative HIV	ND	28.0
6	Positive HCV	27.88	30.33

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