



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 25/04/2024

Doc ID:COA/TP/USPT270/5T

<b>Product Name</b>	Trueprep® AUTO Universal Sample Pre-treatment Pack
<b>Generic Name</b>	Universal Sample Pre-treatment pack for Non MTB samples
<b>Lot No.</b>	USPT270
<b>Mfg. Date</b>	2024-03
<b>Exp. Date</b>	2026-02
<b>Pack Size</b>	5T
<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
<b>A</b>	<b>Contents in the carton (Trueprep® AUTO Universal Sample Pre-treatment Pack)</b>	<b>(Present (P)/Not Present (NP))</b>	
1	Lysis Buffer	Present	Present
2	Disposable Transfer Pipette (1 ml Graduated)	Present	Present
3	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

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Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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)
<b>Negative Control</b>						
1	Negative HBV	ND	Control should be detected	ND	NA	27.22
2	Negative HCV	ND	Control should be detected	ND	NA	26.86
<b>Positive Control</b>						
1	Positive HBV		Test and Control should be detected	29.27	NA	27.49
2	Positive HCV		Test and Control should be detected	29.47	NA	26.67
<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

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

for

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