



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 11/01/2022

Doc ID: COA/TP/ATM077

<b>Brand Name: Trueprep® AUTO Transport Medium for Swab Specimen Pack</b>			
<b>Generic name: Medium for collection, Decontamination and Transport of Swab Specimen for Trueprep® AUTO</b>			
<b>Lot No.: ATM077</b>	<b>Mfg. Date: 2021-10</b>	<b>Exp. Date: 2023-09</b>	<b>A.R. No.: B-ATM-077</b>
<b>Pack size: 50T, 20T, 5T</b>		<b>Storage Temperature: 2°C to 40°C</b>	

**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 Transport Medium for Swab Specimen Pack)	(Present (P)/ Not Present (NP))	
1	Transport Medium	Present	Present
2	Package Insert	Present	Present

Performance on Truelab® micro PCR Analyzers						
Sr. No	Control	Specification (Ct Values)		Test Lot (Ct Values)		
1	Specificity Tests	Test	IC	Test 1 E gene	Test 2 Orf1A	IC
<b>Negative Control</b>						
1	Negative COVID-19	ND	IC should be detected	ND	ND	26.43
2	Negative COVID-19			ND	ND	27.2
3	Negative COVID-19			ND	ND	27.33
<b>Positive Control</b>						
4	Positive COVID-19	Test and IC should be detected		28.29	29.13	24.6
5	Positive COVID-19	Test and IC should be detected		30.13	29.5	23.67
6	Positive COVID-19	Test and IC should be detected		30.75	30.4	24.0

\*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

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