



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 28/04/2021

Doc ID: COA/TP/ATM059

<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.: ATM059</b>	<b>Mfg Date: 2021-04</b>	<b>Exp Date: 2023-03</b>	<b>A.R. No.: B-ATM-059</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

Performance on Truelab® micro PCR Analyzers					
Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
<b>Negative Control</b>					
1	Negative COVID-19	ND	IC should be detected	ND	24.0
2	Negative COVID-19			ND	24.5
3	Negative COVID-19			ND	22.0
<b>Positive Control</b>					
4	Positive COVID-19	Test and IC should be detected		28.43	25.5
5	Positive COVID-19	Test and IC should be detected		27.67	26.2
6	Positive COVID-19	Test and IC should be detected		28.17	26.75

\*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.**

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QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head



## Molbio Diagnostics Private Limited

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