



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 03/06/2021

Doc ID: COA/TP/ATM068

<b>Brand Name: Trueprep<sup>®</sup> AUTO Transport Medium for Swab Specimen Pack</b>			
<b>Generic name: Medium for collection, Decontamination and Transport of Swab Specimen for Trueprep<sup>®</sup> AUTO</b>			
<b>Lot No.: ATM068</b>	<b>Mfg Date: 2021-05</b>	<b>Exp Date: 2023-04</b>	<b>A.R. No.: B-ATM-068</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 <sup>®</sup> AUTO Transport Medium for Swab Specimen Pack)	(Present (P)/ Not Present (NP))	
1	Transport Medium	Present	Present


Performance on Truelab <sup>®</sup> 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	23.75
2	Negative COVID-19			ND	24.4
3	Negative COVID-19			ND	23.2
<b>Positive Control</b>					
4	Positive COVID-19	Test and IC should be detected		30.0	21.2
5	Positive COVID-19	Test and IC should be detected		30.0	23.4
6	Positive COVID-19	Test and IC should be detected		29.8	21.4

\*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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