



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 08//05/2021

Doc ID: COA/TP/ATM061

Brand Name: Trueprep[®] AUTO Transport Medium for Swab Specimen Pack			
Generic name: Medium for collection, Decontamination and Transport of Swab Specimen for Trueprep[®] AUTO			
Lot No.: ATM061	Mfg Date: 2021-04	Exp Date: 2023-03	A.R. No.: B-ATM-061
Pack size: 50T, 20T, 5T		Storage Temperature: 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 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
Negative Control					
1	Negative COVID-19	ND	IC should be detected	ND	27.17
2	Negative COVID-19			ND	24.4
3	Negative COVID-19			ND	24.2
Positive Control					
4	Positive COVID-19	Test and IC should be detected		26.5	21.33
5	Positive COVID-19	Test and IC should be detected		26.6	23.6
6	Positive COVID-19	Test and IC should be detected		26.29	21.56

*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

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