



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 05/04/2021

Doc ID: COA/TP/ATM054

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.: ATM054	Mfg Date: 2021-02	Exp Date: 2023-01	A.R. No.: B-ATM-054
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	24.17
2	Negative COVID-19			ND	23.4
3	Negative COVID-19			ND	27.5
Positive Control					
4	Positive COVID-19	Test and IC should be detected		30.0	23.8
5	Positive COVID-19	Test and IC should be detected		29.13	28.17
6	Positive COVID-19	Test and IC should be detected		28.29	27.6

*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


VERNA
MOLBIO DIAGNOSTICS PVT. LTD.
QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head

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Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

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

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