



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg. Lic. No.: MFG/IVD/2020/000073

Date:19/02/2021

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.: ATM049	Mfg Date: 2020-12	Exp Date: 2022-11	A.R. No.: B-ATM-049
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	22.8
2	Negative COVID-19	ND	IC should be detected	ND	22.2
3	Negative COVID-19	ND	IC should be detected	ND	23.33
Positive Control					
1	Positive COVID-19	Test and IC should be detected		29.0	26.0
2	Positive COVID-19	Test and IC should be detected		28.5	26.6
3	Positive COVID-19	Test and IC should be detected		28.33	26.33

*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
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Designation: QC Head

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Molbio Diagnostics Private Limited

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