

MOLBIO DIAGNOSTICS PRIVATE LIMITED ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/02/2021

Brand Name: True	orep [®] AUTO Transport I	Medium for Swab Spec	imen Pack					
Generic name: Medium for collection, Decontamination and Transport of Swab Specimen for Trueprep® AUTO								
Lot No.: ATM051	Mfg Date: 2021-02	Exp Date: 2023-01	A.R. No.: B-ATM-051					
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	
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	23.75			
2	Negative COVID-19	ND	IC should be detected	ND	24.5			
3	Negative COVID-19	ND		ND	24.2			
Positive Control								
4	Positive COVID-19	Test and IC should be detected		29.0	23.43			
5	Positive COVID-19	Test and	IC should be detected	29.22	24.0			
6	Positive COVID-19	Test and	IC should be detected	30.0	23.75			

^{*}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

Name: Dr. Praveen Kumar Designation:QC Head

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