



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001:2015 & ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 18/04/2020

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.: ATM009	Mfg Date: 2020-04	Exp Date: 2022-03	A.R. No.: B-ATM-009
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	ND	IC should be detected	ND	25.5
2	Negative	ND	IC should be detected	ND	26
Positive Control					
1	Positive	Test and IC should be detected		30.13	27.17
2	Positive	Test and IC should be detected		30.6	26.17

*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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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1Z0