



MOLBIO DIAGNOSTICS PVT. LTD.

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

### CERTIFICATE OF ANALYSIS

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

Date: 19/10/2019

<b>Brand Name: Trueprep® AUTO Transport Medium for Swab Specimen Pack</b>			
<b>Generic name: Medium for collection, Decontamination and Transport of Swab Specimen for Trueprep® AUTO</b>			
<b>Lot No.: ATM006</b>	<b>Mfg Date: 2019-10</b>	<b>Exp Date: 2021-09</b>	<b>A.R. No.: B-ATM-006</b>
<b>Pack size: 20T, 5T</b>		<b>Storage Temperature: 2°C to 40°C</b>	

**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
<b>Negative Control</b>					
1	Negative	ND	IC should be detected	ND	23.75
<b>Positive Control</b>					
1	Positive	Test and IC should be detected		29.6	23
2	Positive	Test and IC should be detected		29	23
3	Positive	Test and IC should be detected		29.8	22.67

\*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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## Molbio Diagnostics Pvt. Ltd.

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