

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2019/000003

**Date:** 07/11/2025

**Doc ID:** COA/TP/ATM115

<b>Product Name</b>	Trueprep <sup>®</sup> AUTO Transport Medium for Swab Specimen Pack
<b>Generic Name</b>	Medium for Collection, Decontamination and Transport of Swab Specimen for Trueprep <sup>®</sup> AUTO
<b>Lot No.</b>	ATM115
<b>Mfg. Date</b>	2025-10
<b>Exp. Date</b>	2027-09
<b>Pack Size</b>	5T, 20T, 25T
<b>Storage condition</b>	2°C to 40°C

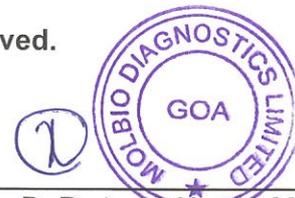
**PRECAUTION:** Refer Safety Data Sheet and follow instructions for use.

Sr. No.	Components in each kit	Specification	Observation
A	<b>Contents in the carton (Trueprep<sup>®</sup> AUTO Transport Medium for Swab Specimen Pack )</b>	<b>(Present (P)/Not Present (NP))</b>	
1	Transport Medium for Swab Specimen Tubes	Present	Present
2	Package Insert	Present	Present

Performance on Truelab <sup>®</sup> Real Time micro PCR Analyzer						
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	Test	IC	Test 1 (Average)	Test 2 (Average)	IC (Average)
<b>Negative Control</b>						
1	Negative COVID-19	ND	Control should be detected	ND	ND	27.29
<b>Positive Control</b>						
1	Positive COVID-19		Test and Control should be detected	21.00	21.23	26.26
<b>Non Template Control Test for COVID-19</b>						
1	NTC		Test 1, Test 2 and Control should not be detected	ND	ND	ND

\*Ct-Cycle Threshold \*IC- Internal Control \*ND- Not Detected \*NA- Not Applicable \*NTC- Non Template Control

The lot is tested and verified as per QC Standards and is approved.



Name: Dr.Praveen Kumar MK

Department: Quality Control

Designation: QC Head