

MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 04/10/2023

Doc ID:COA/TP/ATM094

Product 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.	ATM094				
Mfg. Date	2023-09				
Exp. Date	2025-08				
Pack Size	20T				
Storage condition	2°C to 40°C				

PRECAUTION: Refer Safety Data Sheet and follow instructions for use

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

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	Performance	on True	lab® Real Time	micro PCR A	nalyzer		
Sr. No.	Control		Specification (Ct Values)		Test Lot (Ct Values)		
	Specificity Tests	Test	IC	Test 1 E.gene (Average)	Test 2 Orf1A (Average)	IC (Average)	
Negative Control							
1	Negative COVID-19	ND	Control should be detected	ND	ND	22.46	
Positive	Control						
1	Positive COVID-19		and Control be detected	29.69	29.56	29.12	
Non Ten	plate Control Test fo	r COVID-	19				
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

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.

Name: Dr. Praveer Kumar MK
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Designation: QC Head