



MOLBIO DIAGNOSTICS PVT. LTD.

An ISO 9001 & ISO 13485 certified company

CERTIFICATE OF ANALYSIS

Date: 01/03/18

PRODUCT : Trueprep™ AUTO Transport Medium for Swab Specimen Pack	
Trueprep™ AUTO Transport Medium for Swab Specimen Pack	Lot No.: ATM001 Mfg Date: 2018-02 Exp Date: 2020-01
	A.R. No.: B-ATM-001
Pack size :20 TESTS, 5 TESTS	STORAGE : 2°C to 40°C

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton(TTrueprep™ AUTO Transport Medium for Swab Specimen Pack)(Present (P)/Not Present (NP))		
1	Transport Medium	Present	Present
2	Nylon Floaked Swab	Present	Present

Performance on True Lab Uno					
Sr.No.	CONTROLS	Specification (Ct Values)		Test Lot (Ct Values)	
	Specificity Tests	TEST	IC	TEST	IC
Negative Control					
1	Neg	ND	IC should be detected	ND	19.0
Positive Control					
1	Pos	Test and IC should be detected		26.73	20.5
2	Pos	Test and IC should be detected		26.6	24.2
3	Pos	Test and IC should be detected		27.43	22.67

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE


QUALITY CONTROL
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Designation: QC Head

Page 1 of 1

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