



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 15/09/2021

Doc ID: COA/TP/ATM074

|  |                          |   |                            |
|--|--------------------------|---|----------------------------|
| <b>Brand Name: Trueprep<sup>®</sup> AUTO Transport Medium for Swab Specimen Pack</b>                                     |                          |   |                            |
| <b>Generic name: Medium for collection, Decontamination and Transport of Swab Specimen for Trueprep<sup>®</sup> AUTO</b> |                          |   |                            |
| <b>Lot No.: ATM074</b>   | <b>Mfg Date: 2021-06</b> | <b>Exp Date: 2023-05</b>                | <b>A.R. No.: B-ATM-074</b> |
| <b>Pack size: 50T, 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 <sup>®</sup> AUTO Transport Medium for Swab Specimen Pack) | (Present (P)/ Not Present (NP)) |             |
| 1       | Transport Medium  | Present                         | Present     |


| Performance on Truelab <sup>®</sup> micro PCR Analyzers |                          |                                |                       |                      |       |
|---|--------------------------|--------------------------------|-----------------------|----------------------|-------|
| Sr. No.   | Control                  | Specification (Ct Values)      |                       | Test Lot (Ct Values) |       |
|   |                          | Test                           | IC                    | Test                 | IC    |
| 1   | <b>Specificity Tests</b> |                                |                       |                      |       |
| <b>Negative Control</b>                                 |                          |                                |                       |                      |       |
| 1   | Negative COVID-19        | ND                             | IC should be detected | ND                   | 26.0  |
| 2   | Negative COVID-19        |                                |                       | ND                   | 26.8  |
| 3   | Negative COVID-19        |                                |                       | ND                   | 26.6  |
| <b>Positive Control</b>                                 |                          |                                |                       |                      |       |
| 4   | Positive COVID-19        | Test and IC should be detected |                       | 30.0                 | 26.75 |
| 5   | Positive COVID-19        | Test and IC should be detected |                       | 30.17                | 26.6  |
| 6   | Positive COVID-19        | Test and IC should be detected |                       | 30.6                 | 26.2  |

\*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**

  
QUALITY CONTROL  
Name: Dr. Praveen Kumar  
Designation: QC Head

Page 1 of 1

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO