



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 27/01/2022

Doc ID: COA/TP/ATM078

|   |                           |   |                            |
|---|---------------------------|---|----------------------------|
| <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.: ATM078</b>  | <b>Mfg. Date: 2022-01</b> | <b>Exp. Date: 2023-12</b>               | <b>A.R. No.: B-ATM-078</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® AUTO Transport Medium for Swab Specimen Pack) | (Present (P)/ Not Present (NP)) |             |
| 1       | Transport Medium  | Present                         | Present     |
| 2       | Package Insert  | Present                         | Present     |

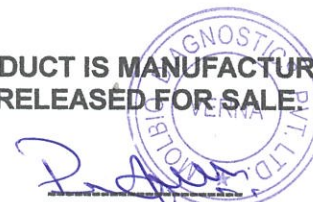
| Performance on Truelab® micro PCR Analyzers |                   |                                |                       |                      |              |       |
|---|-------------------|--------------------------------|-----------------------|----------------------|--------------|-------|
| Sr. No                                      | Control           | Specification (Ct Values)      |                       | Test Lot (Ct Values) |              |       |
| 1   | Specificity Tests | Test                           | IC                    | Test 1 E gene        | Test 2 Orf1A | IC    |
| <b>Negative Control</b>                     |                   |                                |                       |                      |              |       |
| 1   | Negative COVID-19 | ND                             | IC should be detected | ND                   | ND           | 26.0  |
| 2   | Negative COVID-19 |                                |                       | ND                   | ND           | 25.17 |
| 3   | Negative COVID-19 |                                |                       | ND                   | ND           | 24.5  |
| <b>Positive Control</b>                     |                   |                                |                       |                      |              |       |
| 4   | Positive COVID-19 | Test and IC should be detected |                       | 22.5                 | 22.8         | 20.0  |
| 5   | Positive COVID-19 | Test and IC should be detected |                       | 22.29                | 22.6         | 20.5  |
| 6   | Positive COVID-19 | Test and IC should be detected |                       | 22.75                | 23.6         | 20.17 |

\*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**

## Molbio Diagnostics Private Limited

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