



MOLBIO DIAGNOSTICS PRIVATE LIMITED  
ISO 13485:2016 certified company

### CERTIFICATE OF ANALYSIS

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

Date: 08/05/2021

Doc ID: COA/TP/USPT183

|  |   |
|--|---|
| <b>PRODUCT : Trueprep<sup>®</sup> AUTO Universal Sample Pre-treatment Pack</b> |   |
| <b>Trueprep<sup>®</sup> AUTO Universal Sample Pre-treatment Pack</b>           | <b>Lot No.: USPT183 Mfg Date: 2021-05 Exp Date: 2023-04</b> |
|  | <b>A.R. No.: B-USPT-183</b>                                 |
| <b>Pack size : 50T, 20T, 5T</b>  | <b>STORAGE : 2°C to 40°C</b>                                |

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

| Sr. No.  | Components in each kit   | Specification                          | Observation |
|----------|--|--|-------------|
| <b>A</b> | <b>Contents in the carton (Trueprep<sup>®</sup> AUTO Universal Sample Pre- treatment Pack)(Present (P)/Not Present (NP))</b> | <b>(Present (P)/ Not Present (NP))</b> |             |
| 1        | Lysis Buffer   | Present                                | Present     |
| 2        | Disposable Transfer Pipette (1ml)  | Present                                | Present     |

| Performance on Truelab <sup>®</sup> micro PCR Analyzers |                          |                                     |                            |                      |           |
|---|--------------------------|-------------------------------------|----------------------------|----------------------|-----------|
| Sr. No.   | Control                  | Specification (Ct Values)           |                            | Test Lot (Ct Values) |           |
| 1   | <b>Specificity Tests</b> | <b>Test</b>                         | <b>IC</b>                  | <b>Test</b>          | <b>IC</b> |
| <b>Negative Control</b>                                 |                          |                                     |                            |                      |           |
| 1   | Neg HBV                  | ND                                  | Control should be detected | ND                   | 29.0      |
| 2   | Neg COVID-19             | ND                                  | Control should be detected | ND                   | 18.38     |
| 3   | Neg COVID-19             | ND                                  | Control should be detected | ND                   | 20.2      |
| <b>Positive Control</b>                                 |                          |                                     |                            |                      |           |
| 1   | Pos HCV                  | Test and Control should be detected |                            | 30.55                | 29.83     |
| 2   | Pos HIV                  | Test and Control should be detected |                            | 30.33                | 30.0      |
| 3   | Pos HBV                  | Test and Control should be detected |                            | 28.4                 | 29.6      |

\*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  
for Designation: QC Head

## Molbio Diagnostics Private Limited

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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