

**MOLBIO DIAGNOSTICS LIMITED**

EN ISO 13485:2016 certified company

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2021/000064

**Date:** 23/06/2026

**Doc ID:** COA/TP/587VUCPKL

|                          |                                                                                     |
|--------------------------|-------------------------------------------------------------------------------------|
| <b>Product Name</b>      | Trueprep <sup>®</sup> AUTO v2 Universal Cartridge Based Sample Prep Kit             |
| <b>Generic Name</b>      | Sample preparation kit for nucleic acid extraction on Trueprep <sup>®</sup> AUTO v2 |
| <b>Lot No.</b>           | 587VUCPKL                                                                           |
| <b>Mfg. Date</b>         | 2026-05                                                                             |
| <b>Exp. Date</b>         | 2028-04                                                                             |
| <b>Pack Size</b>         | 50T                                                                                 |
| <b>Storage condition</b> | 2°C to 40°C                                                                         |

**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 v2 Universal Cartridge Based Sample prep kit)</b> | <b>[Present (P)/Absent (A)]</b> |                    |
| 1        | Universal Reagent Pack                                                                                 | Should be Present               | P                  |
| 2        | Universal Cartridge Pack                                                                               | Should be Present               | P                  |
| 3        | Disposable Transfer Pipette (3 ml Graduated)                                                           | Should be Present               | P                  |
| 4        | Package Insert                                                                                         | Should be Present               | P                  |
| <b>B</b> | <b>Pouch Seal Integrity</b>                                                                            | <b>Specification</b>            | <b>Observation</b> |
| 1        | Pouch seal integrity test                                                                              | Should Pass                     | Pass               |

| Performance on Truelab® Real Time micro PCR Analyzer |                       |                                                   |                            |                  |                  |                   |
|------------------------------------------------------|-----------------------|---------------------------------------------------|----------------------------|------------------|------------------|-------------------|
| Sr. No.                                              | Specificity Tests     | Specification                                     |                            | Test Lot         |                  |                   |
|                                                      |                       | Test                                              | Control                    | Test 1 (Average) | Test 2 (Average) | Control (Average) |
| Negative Control                                     |                       |                                                   |                            |                  |                  |                   |
| 1                                                    | Negative MTB          | ND                                                | Control should be detected | ND               | NA               | 26.95             |
| 2                                                    | Negative HCV          | ND                                                |                            | ND               | NA               | 27.92             |
| 3                                                    | Negative HIV-1/ HIV-2 | ND                                                |                            | ND               | NA               | 27.91             |
| 4                                                    | Negative MTB Plus     | ND                                                |                            | ND               | NA               | 28.05             |
| Positive Control                                     |                       |                                                   |                            |                  |                  |                   |
| 1                                                    | Positive MTB          | Test and Control should be detected               |                            | 31.00            | NA               | 28.34             |
| 2                                                    | Positive HCV          | Test and Control should be detected               |                            | 32.27            | NA               | 28.11             |
| Non Template Control Test for COVID-19               |                       |                                                   |                            |                  |                  |                   |
| 1                                                    | NTC                   | Test 1, Test 2 and Control should not be detected |                            | ND               | ND               | ND                |

\*Ct-Cycle Threshold \*ND- Not Detected \*NA- Not Applicable \*NTC- Non Template Control

The lot is tested and verified as per QC standards and is approved.

  
**Name:** Dr. Praveen Kumar  
**Department:** Quality Control  
**Designation:** QC Head