

**MOLBIO DIAGNOSTICS LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date:** 17/07/2025

**Doc ID:** COA/TP/318VUCPKL/50T

|                          |                                                                                     |
|--------------------------|-------------------------------------------------------------------------------------|
| <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>           | 318VUCPKL                                                                           |
| <b>Mfg. Date</b>         | 2025-07                                                                             |
| <b>Exp. Date</b>         | 2027-06                                                                             |
| <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)/Not Present (NP))</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.                                              | Control           |                                                   | Specification (Ct Values)  |                  | Test Lot (Ct Values) |              |
|                                                      | Specificity Tests | Test                                              | IC                         | Test 1 (Average) | Test 2 (Average)     | IC (Average) |
| Negative Control                                     |                   |                                                   |                            |                  |                      |              |
| 1                                                    | Negative MTB      | ND                                                | Control should be detected | ND               | NA                   | 27.86        |
| 2                                                    | Negative HBV      | ND                                                |                            | ND               | NA                   | 27.63        |
| 3                                                    | Negative HCV      | ND                                                |                            | ND               | NA                   | 27.44        |
| 4                                                    | Negative HIV-1    | ND                                                |                            | ND               | NA                   | 27.39        |
| 5                                                    | Negative MTB Plus | ND                                                |                            | ND               | NA                   | 28.68        |
| Positive Control                                     |                   |                                                   |                            |                  |                      |              |
| 1                                                    | Positive MTB      | Test and Control should be detected               |                            | 30.45            | NA                   | 26.93        |
| 2                                                    | Positive HCV      | Test and Control should be detected               |                            | 32.22            | NA                   | 28.27        |
| 3                                                    | Positive MTB Plus | Test and Control should be detected               |                            | 30.38            | NA                   | 27.62        |
| 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 \*IC- Internal Control \*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

