

**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

**License No.:** MFG/IVD/2019/000003

**Date:** 16/11/2024

**Doc ID:** COA/TP/VUCPK376L/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>           | VUCPK376L                                                                           |
| <b>Mfg. Date</b>         | 2024-10                                                                             |
| <b>Exp. Date</b>         | 2026-09                                                                             |
| <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                                                                                 | Present                               | Present     |
| 2        | Universal Cartridge Pack                                                                               | Present                               | Present     |
| 3        | Disposable Transfer Pipette (3 ml Graduated)                                                           | Present                               | Present     |
| 4        | Package Insert                                                                                         | Present                               | Present     |

| 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                   | 27.20        |
| 2                                                    | Negative HBV      | ND                                                |                            | ND               | NA                   | 27.34        |
| 3                                                    | Negative HCV      | ND                                                |                            | ND               | NA                   | 27.03        |
| 4                                                    | Negative HIV-1    | ND                                                |                            | ND               | NA                   | 27.25        |
| 5                                                    | Negative MTB Plus | ND                                                |                            | ND               | NA                   | 27.50        |
| Positive Control                                     |                   |                                                   |                            |                  |                      |              |
| 1                                                    | Positive MTB      | Test and Control should be detected               |                            | 24.28            | NA                   | 28.04        |
| 2                                                    | Positive HCV      | Test and Control should be detected               |                            | 30.53            | NA                   | 26.18        |
| 3                                                    | Positive MTB Plus | Test and Control should be detected               |                            | 23.79            | NA                   | 27.31        |
| 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. Prayeen Kumar MK  
**Department:** Quality Control  
**Designation:** QC Head