



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 11/11/2024

Doc ID:COA/TP/VUCPK373L/50T

|                   |                                                                         |
|-------------------|-------------------------------------------------------------------------|
| Product Name      | Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit             |
| Generic Name      | Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2 |
| Lot No.           | VUCPK373L                                                               |
| Mfg. Date         | 2024-06                                                                 |
| Exp. Date         | 2026-05                                                                 |
| Pack Size         | 50T                                                                     |
| Storage condition | 2°C to 40°C                                                             |

**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 v2 Universal Cartridge Based Sample prep kit) | (Present (P)/Not Present (NP)) |             |
| 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     |

**Molbio Diagnostics Private Limited**

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



| 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                   | 28.57        |
| 2                                                    | Negative HBV      | ND                                                |                            | ND               | NA                   | 26.23        |
| 3                                                    | Negative HCV      | ND                                                |                            | ND               | NA                   | 27.60        |
| 4                                                    | Negative HIV-1    | ND                                                |                            | ND               | NA                   | 27.31        |
| 5                                                    | Negative MTB Plus | ND                                                |                            | ND               | NA                   | 27.58        |
| Positive Control                                     |                   |                                                   |                            |                  |                      |              |
| 1                                                    | Positive MTB      | Test and Control should be detected               |                            | 23.28            | NA                   | 27.15        |
| 2                                                    | Positive HIV      | Test and Control should be detected               |                            | 29.38            | NA                   | 27.84        |
| 3                                                    | Positive MTB Plus | Test and Control should be detected               |                            | 23.21            | NA                   | 26.92        |
| 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 MK  
**Department:** Quality Control  
**Designation:** QC Head