



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 10/02/2024

Doc ID: COA/TP/076VUCPKL

|                   |                                                                         |
|-------------------|-------------------------------------------------------------------------|
| 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.           | 076VUCPKL                                                               |
| Mfg. Date         | 2024-01                                                                 |
| Exp. Date         | 2025-12                                                                 |
| Pack Size         | 50T                                                                     |
| Storage condition | 2°C to 40°C                                                             |

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

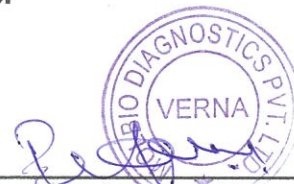
| Sr. No. | Components in each kit                                                               | Specification                  | Observation |
|---------|--------------------------------------------------------------------------------------|--------------------------------|-------------|
| A       | 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     |



| 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                   | 26.14        |
| 2                                                    | Negative HBV      | ND                                                |                            | ND               | NA                   | 28.76        |
| 3                                                    | Negative HCV      | ND                                                |                            | ND               | NA                   | 27.80        |
| 4                                                    | Negative HIV-1    | ND                                                |                            | ND               | NA                   | 27.62        |
| Positive Control                                     |                   |                                                   |                            |                  |                      |              |
| 1                                                    | Positive MTB      | Test and Control should be detected               |                            | 30.10            | NA                   | 26.41        |
| 2                                                    | Positive HCV      | Test and Control should be detected               |                            | 30.58            | NA                   | 27.76        |
| 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

**Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.**



**Name:** Dr.Praveen Kumar MK  
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**Designation:**QC Head

## Molbio Diagnostics Private Limited

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