



MOLBIO DIAGNOSTICS PRIVATE LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 27/06/2023

Doc ID: COA/TP/VUCPK284

|                   |   |
|-------------------|---|
| 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.           | VUCPK284  |
| Mfg. Date         | 2023-02   |
| Exp. Date         | 2025-01   |
| Pack Size         | 05T, 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

Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

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) |
| <b>Negative Control</b>                              |                   |   |                            |                  |                      |              |
| 1  | Negative MTB      | ND  | Control should be detected | ND               | NA                   | 28.09        |
| 2  | Negative HBV      | ND  |                            | ND               | NA                   | 26.93        |
| 3  | Negative HCV      | ND  |                            | ND               | NA                   | 27.6         |
| 4  | Negative HIV      | ND  |                            | ND               | NA                   | 26.55        |
| <b>Positive Control</b>                              |                   |   |                            |                  |                      |              |
| 1  | Positive MTB      | Test and Control should be detected               |                            | 30.05            | NA                   | 28.22        |
| 2  | Positive HCV      | Test and Control should be detected               |                            | 29.21            | NA                   | 27.71        |
| <b>Non Template Control Test for COVID-19</b>        |                   |   |                            |                  |                      |              |
| 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  
**Department:** Quality Control  
**Designation:** QC Head

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