



**MOLBIO DIAGNOSTICS PRIVATE LIMITED**

**EN ISO 13485:2016 certified company**

**CERTIFICATE OF ANALYSIS**

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

**Date:** 15/01/2024

**Doc ID:** COA/TP/070VUCPK

|                          |                                                                         |
|--------------------------|-------------------------------------------------------------------------|
| <b>Product Name</b>      | Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit             |
| <b>Generic Name</b>      | Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2 |
| <b>Lot No.</b>           | 070VUCPK                                                                |
| <b>Mfg. Date</b>         | 2023-11                                                                 |
| <b>Exp. Date</b>         | 2025-10                                                                 |
| <b>Pack Size</b>         | 50T                                                                     |
| <b>Storage condition</b> | 2°C to 40°C                                                             |

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

| <b>Sr. No.</b> | <b>Components in each kit</b>                                                               | <b>Specification</b>                  | <b>Observation</b> |
|----------------|---------------------------------------------------------------------------------------------|---------------------------------------|--------------------|
| <b>A</b>       | <b>Contents in the carton (Trueprep® 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                   | 26.48        |
| 2                                                    | Negative HBV      | ND                                                |                            | ND               | NA                   | 27.20        |
| 3                                                    | Negative HCV      | ND                                                |                            | ND               | NA                   | 27.71        |
| 4                                                    | Negative HIV-1    | ND                                                |                            | ND               | NA                   | 28.31        |
| Positive Control                                     |                   |                                                   |                            |                  |                      |              |
| 1                                                    | Positive MTB      | Test and Control should be detected               |                            | 30.13            | NA                   | 27.33        |
| 2                                                    | Positive HCV      | Test and Control should be detected               |                            | 30.07            | NA                   | 27.87        |
| 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