



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company
CERTIFICATE OF ANALYSIS

Mfg.Lic. No.: MFG/IVD/2019/000003

Date: 16/06/2021

Doc ID: COA/TP/VUCPK141-P

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|--|--|
| Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit | |
| Trueprep® AUTO Universal Cartridge Based Sample Prep Kit | Lot No.: VUCPK141-P Mfg Date: 2021-05 Exp Date: 2023-04 |
| | A.R. No.: B-VUCPK-141-P |
| Pack size: 5, 25, 50 TESTS | Storage: 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 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) | Present | Present |
| 4 | Package Insert | Present | Present |

| Performance on Truelab® micro PCR Analyzers | | | |
|--|--------------------------|--------------------------|----------------|
| Sr. No. | Sample Negative/Positive | Negative: Test- ND | IC- Detected |
| | | Positive: Test- Detected | IC- Detected |
| | | Test (Ct) | IC (Ct) |
| 1 | Positive MTB | 27.6 | 27.5 |
| 2 | Positive MTB | 27.6 | 28.0 |
| 3 | Negative HIV | ND | 30.33 |
| 4 | Positive Dengue | 30.8 | 29.8 |
| 5 | Positive HCV | 31.13 | 30.13 |

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

Molbio Diagnostics Private Limited

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| Pack size: 5, 25, 50 TESTS | Storage: 2°C to 40°C |

| Performance on Truelab® micro PCR Analyzers | | | |
|--|-------------------|-------|-------|
| 6 | Positive HIV | 31.25 | 28.67 |
| 7 | Positive HIV | 30.0 | 28.6 |
| 8 | Negative COVID-19 | ND | 20.33 |
| 9 | Negative COVID-19 | ND | 29.4 |
| 10 | Positive HBV | 28.33 | 29.2 |

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE


QUALITY CONTROL
Name: Dr. Praveen Kumar
Designation: QC Head