



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 15/04/2021

Doc ID: COA/TP/VUCPK111-P

| | |
|--|---|
| Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit | |
| Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit | Lot No.: VUCPK111-P Mfg Date: 2021-03 Exp Date: 2023-02 |
| | A.R. No.: B-VUCPK-111-P |
| Pack size: 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 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) | Present | Present |
| 4 | Package Insert | Present | Present |

Performance on Truelab® micro PCR Analyzers

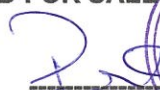

| Sr. No. | Sample Negative/Positive | Negative: Test- ND | IC- Detected |
|---------|-----------------------------|--------------------------|--------------|
| | | Positive: Test- Detected | IC- Detected |
| | | Test (Ct) | IC (Ct) |
| 1 | Negative MTB | ND | 29.8 |
| 2 | Positive MTB | 28.33 | 28.14 |
| 3 | Negative HBV | ND | 30.22 |
| 4 | Positive HBV | 29.83 | 29.67 |
| 5 | Positive HCV | 29.75 | 29.33 |
| 6 | Positive HIV | 28.8 | 30.6 |

*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

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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

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