



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

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

Date: 28/01/2022

Doc ID: COA/TP/VUCPK232-PLM

| | | |
|---|-----------------------------|----------------------------------|
| Product: Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit | | |
| Lot No.: VUCPK232-PLM | Mfg. Date: 2022-01 | Exp. Date: 2023-12 |
| Pack size: 50T, 5T | Storage: 2°C to 40°C | A.R. No.: B-VUCPK-232-PLM |

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 HBV | ND | 29.57 |
| 2 | Negative MTB | ND | 29.6 |
| 3 | Negative COVID-19 | ND | 25.17 |
| 4 | Positive HBV | 28.33 | 27.6 |
| 5 | Positive HBV | 28.67 | 28.83 |
| 6 | Positive HCV | 30.91 | 28.33 |

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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| 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) |
| 7 | Positive HCV | 30.6 | 28.86 |
| 8 | Positive HIV | 30.67 | 29.2 |
| 9 | Positive MTB | 27.29 | 29 |
| 10 | Positive MTB | 27 | 28 |

*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