



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

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

Date: 21/09/2021

Doc ID: COA/TP/USPK480-PL

| | | |
|--|-----------------------------|--------------------------------|
| Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit | | |
| Lot No.: USPK480-PL | Mfg Date: 2020-11 | Exp Date: 2022-11 |
| Pack size: 5, 25, 50 TESTS | Storage: 2°C to 40°C | A.R. No.: B-USPK-480-PL |

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 Positive: Test- Detected | IC- Detected IC- Detected |
|---------|-----------------------------|--|------------------------------|
| | | Test (Ct) | IC (Ct) |
| 1 | Negative HBV | ND | 29.6 |
| 2 | Negative HCV | ND | 28.4 |
| 3 | Positive HBV | 28.43 | 28.33 |
| 4 | Positive HBV | 28.17 | 29.15 |
| 5 | Positive HCV | 29.42 | 28.67 |
| 6 | Positive HIV | 30 | 29.4 |
| 7 | Negative MTB | ND | 29.29 |

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



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

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

Date: 21/09/2021

Doc ID: COA/TP/USPK480-PL

| | | |
|---|----------------------|-------------------------|
| Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit | | |
| Lot No.: USPK480-PL | Mfg Date: 2020-11 | Exp Date: 2022-11 |
| Pack size: 5, 25, 50 TESTS | Storage: 2°C to 40°C | A.R. No.: B-USPK-480-PL |

| Performance on Truelab® micro PCR Analyzers | | | |
|---|-----------------------------|--|------------------------------|
| Sr. No. | Sample Negative/Positive | Negative: Test- ND Positive: Test- Detected | IC- Detected IC- Detected |
| | | Test (Ct) | IC (Ct) |
| 8 | Positive MTB | 28 | 27.75 |
| 9 | Negative COVID-19 | ND | 27.4 |
| 10 | Positive COVID-19 | 30 | 22.33 |

*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

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