



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

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

Date: 01/11/2021

Doc ID: COA/TP/USPK492-PL

| | | |
|---|----------------------|-------------------------|
| Product: Trueprep [®] AUTO Universal Cartridge Based Sample Prep Kit | | |
| Lot No.: USPK492-PL | Mfg. Date: 2021-07 | Exp. Date: 2023-06 |
| Pack size: 5, 25, 50 TESTS | Storage: 2°C to 40°C | A.R. No.: B-USPK-492-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 | IC- Detected |
|---------|--------------------------|--------------------------|--------------|
| | | Positive: Test- Detected | IC- Detected |
| | | Test (Ct) | IC (Ct) |
| 1 | Negative HBV | ND | 30.17 |
| 2 | Negative Dengue | ND | 30.8 |
| 3 | Negative COVID-19 | ND | 26.17 |
| 4 | Negative MTB | ND | 28.5 |
| 5 | Positive MTB | 28.29 | 30.0 |



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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) |
| 6 | Positive MTB | 27.5 | 27.75 |
| 7 | Positive HBV | 28.67 | 30.43 |
| 8 | Positive HBV | 29.14 | 31.0 |
| 9 | Positive HCV | 32.14 | 29.6 |
| 10 | Positive HIV | 29.5 | 30.0 |

*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