



MOLBIO DIAGNOSTICS PVT. LTD.
An ISO 9001:2015 & ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 14/01/2020

| | |
|---|--|
| Product: Trueprep® AUTO Universal Cartridge Based Sample prep kit | |
| Trueprep® AUTO Universal Cartridge Based Sample prep kit | Lot No.: USPK252 Mfg Date: 2019-09 Exp Date: 2021-08 |
| | A.R. No.: B-USPK-252 |
| Pack size: 5, 25 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 | Negative MTB | ND | 28.25 |
| 2 | Positive MTB | 27.2 | 28.6 |
| 3 | Positive MTB | 27.33 | 27.67 |
| 4 | Positive MTB | 26.75 | 28.33 |

*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



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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO