



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

### CERTIFICATE OF ANALYSIS

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

Date: 08/01/2020

|   |  |
|---|--|
| Product: Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample prep kit |  |
| Trueprep <sup>®</sup> AUTO Universal Cartridge Based Sample prep kit          | Lot No.: USPK250 Mfg Date: 2019-12 Exp Date: 2021-11 |
|   | A.R. No.: B-USPK-250                                 |
| 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 <sup>®</sup> 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 <sup>™</sup> 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           |
| 2   | Positive MTB             | 30                       | 28.29        |
| 3   | Negative HBV             | ND                       | 29.67        |
| 4   | Positive HBV             | 29.6                     | 29.6         |
| 5   | Positive HCV             | 30.8                     | 29.2         |
| 6   | Positive HIV             | 27.5                     | 29.8         |

\*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

Page 1 of 1

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