

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2019/000003

Date: 09/10/2025

Doc ID: COA/TP/VUCPK480L

| | |
|--------------------------|---|
| Product Name | Trueprep [®] AUTO v2 Universal Cartridge Based Sample Prep Kit |
| Generic Name | Sample preparation kit for nucleic acid extraction on Trueprep [®] AUTO v2 |
| Lot No. | VUCPK480L |
| Mfg. Date | 2025-08 |
| Exp. Date | 2027-07 |
| Pack Size | 50T |
| Storage condition | 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 v2 Universal Cartridge Based Sample prep kit) | | |
| 1 | Universal Reagent Pack | Should be Present | Present |
| 2 | Universal Cartridge Pack | Should be Present | Present |
| 3 | Disposable Transfer Pipette (3 ml Graduated) | Should be Present | Present |
| 4 | Package Insert | Should be Present | Present |
| 5 | Desiccant pouch | Should be Present | Present |
| 6 | Colour of desiccant pouch | Should be Orange in Colour | Orange Colour |
| B | Seal integrity test | Should Pass | Pass |

| Performance on Truelab® Real Time micro PCR Analyzer | | | | | | |
|--|-------------------|---|----------------------------|------------------|----------------------|--------------|
| Sr. No. | Control | | Specification (Ct Values) | | Test Lot (Ct Values) | |
| | Specificity Tests | Test | IC | Test 1 (Average) | Test 2 (Average) | IC (Average) |
| Negative Control | | | | | | |
| 1 | Negative MTB | ND | Control should be detected | ND | NA | 26.72 |
| 2 | Negative HBV | ND | | ND | NA | 27.15 |
| 3 | Negative HCV | ND | | ND | NA | 26.84 |
| 4 | Negative HIV-1 | ND | | ND | NA | 27.96 |
| 5 | Negative MTB Plus | ND | | ND | NA | 26.89 |
| Positive Control | | | | | | |
| 1 | Positive MTB | Test and Control should be detected | | 30.19 | NA | 26.41 |
| 2 | Positive HCV | Test and Control should be detected | | 32.27 | NA | 26.65 |
| 3 | Positive MTB Plus | Test and Control should be detected | | 31.01 | NA | 26.47 |
| Non Template Control Test for COVID-19 | | | | | | |
| 1 | NTC | Test 1, Test 2 and Control should not be detected | | ND | ND | ND |

*Ct-Cycle Threshold
Template Control

*IC- Internal Control

*ND- Not Detected

*NA- Not Applicable

*NTC- Non

The lot is tested and verified as per QC Standards and is approved.



for

Name: Dr.Praveen Kumar MK

Department: Quality Control

Designation: QC Head

FM/QT/224-03

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