

MOLBIO DIAGNOSTICS LIMITED

EN ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date: 20/02/2026

Doc ID: COA/TP/486VUCPKL

| | |
|--------------------------|---|
| 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. | 486VUCPKL |
| Mfg. Date | 2026-02 |
| Exp. Date | 2028-01 |
| 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) | [Present (P)/Absent (A)] | |
| 1 | Universal Reagent Pack | Should be Present | P |
| 2 | Universal Cartridge Pack | Should be Present | P |
| 3 | Disposable Transfer Pipette (3 ml Graduated) | Should be Present | P |
| 4 | Package Insert | Should be Present | P |
| B | Pouch Seal Integrity | Specification | Observation |
| 1 | Pouch seal integrity test | Should Pass | Pass |

| Performance on Truelab [®] Real Time micro PCR Analyzer | | | | | | |
|--|-------------------|-------------------------------------|----------------------------|------------------|------------------|-------------------|
| Sr. No. | Specificity Tests | Specification | | Test Lot | | |
| | | Test | Control | Test 1 (Average) | Test 2 (Average) | Control (Average) |
| Negative Control | | | | | | |
| 1 | Negative MTB | ND | Control should be detected | ND | NA | 26.86 |
| 2 | Negative HCV | ND | | ND | NA | 27.76 |
| 3 | Negative HIV-1 | ND | | ND | NA | 26.74 |
| 4 | Negative MTB Plus | ND | | ND | NA | 28.20 |
| Positive Control | | | | | | |
| 1 | Positive MTB | Test and Control should be detected | | 30.63 | NA | 26.87 |
| 2 | Positive HCV | Test and Control should be detected | | 32.03 | NA | 27.53 |
| 3 | Positive MTB Plus | Test and Control should be detected | | 30.33 | NA | 28.55 |

| 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 *ND- Not Detected *NA- Not Applicable *NTC- Non Template Control

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



Name: Dr. Praveen Kumar
Department: Quality Control
Designation: QC Head