



MOLBIO DIAGNOSTICS PRIVATE LIMITED

ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

License No.: MFG/IVD/2021/000064

Date:24/03/2023

Doc ID:COA/TP/013VUCPK

| | |
|--------------------------|---|
| 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. | 013VUCPK |
| Mfg. Date | 2023-01 |
| Exp. Date | 2024-12 |
| Pack Size | 5T, 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)/Not Present (NP)) | |
| 1 | Universal Reagent Pack | Present | Present |
| 2 | Universal Cartridge Pack | Present | Present |
| 3 | Disposable Transfer Pipette (3 ml Graduated) | Present | Present |
| 4 | Package Insert | Present | Present |

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Regd. Office & Works: Plot No. L-46, Phase II D, Verna Industrial Estate, Verna - Goa 403 722. INDIA

Tel: +91-832-6724888 / 2783267 Email: admin@molbiodiagnostics.com

Email: sales@molbiodiagnostics.com Website: www.molbiodiagnostics.com

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



| 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 | 28.63 |
| 2 | Negative HBV | ND | | ND | NA | 27.13 |
| 3 | Negative HCV | ND | | ND | NA | 27.24 |
| 4 | Negative HIV | ND | | ND | NA | 27.32 |
| Positive Control | | | | | | |
| 1 | Positive MTB | Test and Control should be detected | | 30.68 | NA | 28.53 |
| 2 | Positive HIV | Test and Control should be detected | | 30.04 | NA | 27.93 |

*Ct-Cycle Threshold *IC- Internal Control *ND- Not Detected *NA- Not Applicable

Manufacturing records are verified, checked and product is manufactured as per the GMP, samples tested and lot is QC approved for sale purpose.



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

for

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