



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg.Lic. No. : MFG/IVD/2020/000003

Date: 10/02/2021

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|--|--|
| PRODUCT : Trueprep[®] AUTO Universal Sample Pre-treatment Pack | |
| Trueprep [®] AUTO Universal Sample Pre-treatment Pack | Lot No.: USPT144 Mfg Date: 2021-01 Exp Date: 2022-12 A.R. No.: B-USPT-144 |
| Pack size : 50T, 20T, 5T | 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 Sample Pre- treatment Pack)(Present (P)/Not Present (NP)) | (Present (P)/ Not Present (NP)) | |
| 1 | Lysis Buffer | Present | Present |
| 2 | Disposable Transfer Pipette (1ml) | Present | Present |

| Performance on Truelab [®] micro PCR Analyzers | | | | | |
|---|-------------------|-------------------------------------|----------------------------|----------------------|------|
| Sr. No. | Control | Specification (Ct Values) | | Test Lot (Ct Values) | |
| 1 | Specificity Tests | Test | IC | Test | IC |
| Negative Control | | | | | |
| 1 | Neg HBV | ND | Control should be detected | ND | 28.8 |
| 2 | Neg HIV | ND | Control should be detected | ND | 28 |
| 3 | Neg COVID-19 | ND | Control should be detected | ND | 24 |
| Positive Control | | | | | |
| 1 | Pos HBV | Test and Control should be detected | | 31.14 | 30 |
| 2 | Pos HCV | Test and Control should be detected | | 27.7 | 28 |
| 3 | Pos COVID-19 | Test and Control should be detected | | 29.67 | 26.4 |

*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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Molbio Diagnostics Private Limited

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