



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg.Lic. No. : MFG/IVD/2020/000119

Date: 19/06/2021

Doc ID: COA/TP/USPT213

| | |
|--------------------------------------------------------------------------------|------------------------------------------------------|
| PRODUCT : Trueprep[®] AUTO Universal Sample Pre-treatment Pack | |
| Trueprep [®] AUTO Universal Sample Pre-treatment Pack | Lot No.: USPT213 Mfg Date: 2021-05 Exp Date: 2023-04 |
| | A.R. No.: B-USPT-213 |
| 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) | |
|-------------------------|--------------|-------------------------------------|----------------------------|----------------------|-------|
| | | Test | IC | Test | IC |
| Negative Control | | | | | |
| 1 | Neg HBV | ND | Control should be detected | ND | 28.83 |
| 2 | Neg COVID-19 | ND | Control should be detected | ND | 21.33 |
| Positive Control | | | | | |
| 1 | Pos HIV | Test and Control should be detected | | 31.17 | 28.83 |
| 2 | Pos HCV | Test and Control should be detected | | 31.78 | 29.8 |
| 3 | Pos HBV | Test and Control should be detected | | 28.5 | 30.13 |
| 4 | Pos COVID-19 | Test and Control should be detected | | 28.33 | 25.6 |

*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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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO