molbio®

MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg.Lic. No.: MFG/IVD/2019/000003

Date: 22/09/2021
Doc ID: COA/TP/USPK481-PL

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit		
Lot No.: USPK481-PL	**Mfg Date: 2021-07**	**Exp Date: 2023-06**
Pack size: 5, 25, 50 TESTS	**Storage: 2°C to 40°C**	**A.R. No.: B-USPK-481-PL**

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 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)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab® micro PCR Analyzers			
Sr. No.	**Sample Negative/Positive**	**Negative:** Test- ND IC- Detected **Positive:** Test- Detected IC- Detected	
		Test (Ct)	**IC (Ct)**
1	Negative HBV	ND	29.5
2	Positive HBV	28.14	30.29
3	Positive HBV	29.1	29.88
4	Positive HCV	29.55	28.5
5	Positive HIV	30.33	29.75
6	Negative MTB	ND	29.67
7	Positive MTB	28.29	29.33

Molbio Diagnostics Private Limited

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

molbio®

MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

Mfg.Lic. No.: MFG/IVD/2019/000003

Date: 22/09/2021
Doc ID: COA/TP/USPK481-PL

Product: Trueprep® AUTO Universal Cartridge Based Sample Prep Kit		
Lot No.: USPK481-PL	**Mfg Date: 2021-07**	**Exp Date: 2023-06**
Pack size: 5, 25, 50 TESTS	**Storage: 2°C to 40°C**	**A.R. No.: B-USPK-481-PL**

Performance on Truelab® micro PCR Analyzers			
Sr. No.	**Sample Negative/Positive**	**Negative:** Test- ND IC- Detected **Positive:** Test- Detected IC- Detected	
		Test (Ct)	**IC (Ct)**
8	Positive MTB	28.75	29.17
9	Negative COVID-19	ND	27.8
10	Positive COVID-19	29.43	22.17

*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

MOLBIO DIAGNOSTICS PVT. LTD. VERNA

QUALITY CONTROL
Name: Dr. Praveen Kumar
for **Designation: QC Head**

Molbio Diagnostics Private Limited

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