



MOLBIO DIAGNOSTICS PVT. LTD.
An ISO 9001:2015 & ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 25/10/2019

PRODUCT : Trueprep™ AUTO Universal Sample Pre-treatment Pack	
Trueprep™ AUTO Universal Sample Pre-treatment Pack	Lot No.: USPT024 Mfg Date: 2019-10 Exp Date: 2021-09
	A.R. No.: B-USPT-024
Pack size : 20 TESTS, 5 TESTS	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))		
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	28.6
Positive Control					
1	Pos HBV	Test and Control should be detected		28.17	28.83
2	Pos DEN	Test and Control should be detected		26.14	28.86
3	Pos HCV	Test and Control should be detected		27.07	28.14

*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

Page 1 of 1

Molbio Diagnostics Pvt. Ltd.

Regd. Office: H. No. 13, Sagar Society, Dona Paula, Panaji, North Goa 403 004. INDIA

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

Tel: +91-832-2783267 E mail: admin@molbiodiagnostics.com

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

CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO