



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

CERTIFICATE OF ANALYSIS

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

Date: 10/05/2019

PRODUCT : Trueprep™ AUTO Universal Cartridge Based Sample prep kit

Trueprep™ AUTO Universal
Cartridge Based
Sample prep kit

Lot No.: USPK152 Mfg Date: 2019-04 Exp Date: 2021-03
A.R. No.: B-USPK-152

Pack size : 5, 25 TESTS

STORAGE : 2°C to 40°C

PRECAUTION: The product is offered without warranty for any other specific use than that specified in the 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

Sr.No.	Sample Neagtive/Positive	Negative:TEST-ND	Control-Detected
		Positive:TEST-Detected	Control-Detected
		TEST	Control
01	Negative MTB	ND	28.14
02	Positive MTB	27.0	29.0
03	Negative HBV	ND	27.67
04	Positive HBV	28.5	27.33
05	Positive HCV	28.89	29.11
06	Positive HIV	27.83	29.0

MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE


QUALITY CONTROL
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