



MOLBIO DIAGNOSTICS PRIVATE LIMITED
ISO 13485:2016 certified company

CERTIFICATE OF ANALYSIS

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

Date: 02/10/2021

Doc ID: COA/SF/SPF002

Brand Name: STABILYSE[®] Prep Free			
Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen			
Lot No.: SPF002	Mfg Date: 2021-09	Exp Date: 2023-08	A.R. No.: B-SPF-002
Pack size: 50T		Storage Temperature: 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 (STABILYSE [®] Prep Free)	(Present (P)/ Not Present (NP))	
1	Collection and Lysis Medium Tube	Present	Present
2	Pack Insert	Present	Present

Performance on Truelab[®] micro PCR Analyzers

Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)		
		Test	IC	Test 1: E gene	Test 2: Orf 1A	IC
Negative Control						
1	Negative COVID-19	ND	IC should be detected	ND	ND	24.75
2	Negative COVID-19	ND	IC should be detected	ND	ND	24.75
3	Negative COVID-19	ND	IC should be detected	ND	ND	26.2
Positive Control						
1	Positive COVID-19	Test and IC should be detected		22.33	20.13	26.0
2	Positive COVID-19	Test and IC should be detected		22.6	20.13	26.2
3	Positive COVID-19	Test and IC should be detected		21.8	19.86	26.17

*Ct- Cycle threshold

*IC- Internal Control

*ND- Not Detected

Note: For swab specimen the human *RNase P* gene serves as a full process internal positive control (IPC)

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

Molbio Diagnostics Private Limited

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CIN: U33125GA2000PTC002909 GSTN:30AACCM8275E1ZO



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CERTIFICATE OF ANALYSIS

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

Date:18/12/2021

Doc.ID:COA/TP/USPT230

Product: Trueprep® AUTO Universal Sample Pre-treatment Pack		
Lot No.: USPT230	Mfg. Date: 2021-12	Exp. Date: 2023-11
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-USPT-230

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	Package Insert	Present	Present
3	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	Negative HBV	ND	Control should be detected	ND	29.5
2	Negative COVID-19	ND	Control should be detected	ND	26.0
3	Negative COVID-19	ND	Control should be detected	ND	26.0
4	Negative Dengue	ND	Control should be detected	ND	30.0
Positive Control					
1	Positive HBV	Test and Control should be detected		28.5	30.67
2	Positive HBV	Test and Control should be detected		28.14	28.8
3	Positive HCV	Test and Control should be detected		29.5	30.4
4	Positive HIV	Test and Control should be detected		27.0	27.0

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Page 1 of 1

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CERTIFICATE OF ANALYSIS

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

Date: 13/12/2021

Doc ID:COA/TP/MSPT120

Product: Trueprep [®] AUTO MTB Sample Pre-treatment Pack		
Lot No.: MSPT120	Mfg. Date: 2021-10	Exp. Date: 2023-09
Pack size: 50T, 20T, 5T	Storage: 2°C to 40°C	A.R. No.: B-MSPT-120

PREAUTION: Refer Safety Data Sheet and follow instructions for use

Sr. No.	Components in each kit	Specification	Observation
A	Contents in the carton (MTB Sample Pre-treatment Pack)	(Present (P)/Not Present (NP))	
1	Lysis Buffer	Present	Present
2	Liquefaction Buffer	Present	Present
3	Disposable Transfer Pipette (1ml)	Present	Present
4	Package Insert	Present	Present

Performance on Truelab [®] Real Time micro PCR Analyzers					
Sr. No.	Controls	Specification (Ct Values)		Test Lot (Ct Values)	
1	Specificity Tests	Test	IC	Test	IC
Negative Control					
1	Negative MTB	ND	Control should be detected	ND	29.33
2	Negative MTB	ND	Control should be detected	ND	27.2
3	Negative MTB	ND	Control should be detected	ND	29.33
Positive Control					
1	Positive MTB	Test and Control should be detected		27.0	28.5
2	Positive MTB	Test and Control should be detected		26.0	28.8
3	Positive MTB	Test and Control should be detected		28.2	30.29

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CERTIFICATE OF ANALYSIS

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

Date: 21/09/2021

Doc ID: COA/SF/SPF001

Brand Name: STABILYSE® Prep Free			
Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen			
Lot No.: SPF001	Mfg Date: 2021-09	Exp Date: 2023-08	A.R. No.: B-SPF-001
Pack size: 50T		Storage Temperature: 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 (STABILYSE® Prep Free)	(Present (P)/ Not Present (NP))	
1	Collection and Lysis Medium Tube	Present	Present
2	Pack Insert	Present	Present

Performance on Truelab® micro PCR Analyzers

Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)		
		Test	IC	Test 1: E gene	Test 2: Orf 1A	IC
Negative Control						
1	Negative COVID-19	ND	IC should be detected	ND	ND	22.29
2	Negative COVID-19	ND	IC should be detected	ND	ND	21.2
3	Negative COVID-19	ND	IC should be detected	ND	ND	21.25
Positive Control						
1	Positive COVID-19	Test and IC should be detected		22.5	21.13	21.75
2	Positive COVID-19	Test and IC should be detected		22.57	21.3	20.4
3	Positive COVID-19	Test and IC should be detected		23	20.88	22.0

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

Date: 18/10/2021

Doc ID: COA/SF/SPF004

Brand Name: STABILYSE® Prep Free			
Generic name: Sample Collection and Lysis Medium for Prep Free Swab Specimen			
Lot No.: SPF004	Mfg Date: 2021-10	Exp Date: 2023-09	A.R. No.: B-SPF-004
Pack size: 50T		Storage Temperature: 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 (STABILYSE® Prep Free)	(Present (P)/ Not Present (NP))	
1	Collection and Lysis Medium Tube	Present	Present
2	Pack Insert	Present	Present

Performance on Truelab® micro PCR Analyzers

Sr. No.	Control	Specification (Ct Values)		Test Lot (Ct Values)		
		Test	IC	Test 1: E gene	Test 2: Orf 1A	IC
Negative Control						
1	Negative COVID-19	ND	IC should be detected	ND	ND	23.29
2	Negative COVID-19	ND	IC should be detected	ND	ND	23.33
3	Negative COVID-19	ND	IC should be detected	ND	ND	23.29
Positive Control						
1	Positive COVID-19	Test and IC should be detected		23	21.22	20.5
2	Positive COVID-19	Test and IC should be detected		23	21.6	21.6
3	Positive COVID-19	Test and IC should be detected		23.5	21.5	22.0

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