

DIESSE DIAGNOSTICA SENESE SpA
 53035 Monteriggioni (SI) – Italia – Via delle Rose 10
 Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
 20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL SARS-CoV-2 IgM

Code	91401				
LOT.NO	016		2022-10		2022-02

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93101	B4161	MICROPLATE	046	2022-10	1
PF94501	F4160	CONJUGATE	013	2023-05	1
PF93400	C4151	NEGATIVE CONTROL	014	2023-02	1
PF93801	E4160	POSITIVE CONTROL	013	2023-02	1
PF91801	D4160	CUT-OFF CONTROL	013	2023-02	1
PF30401	G4160	SAMPLE SORBENT 4	009	2023-08	1
PF93611	009660	DILUENT 2	222	2023-08	1
PF93603	1035	WASHING BUFFER 10X	446	2023-07	1
PF93602	1032/RISK0	STOP SOLUTION	214	2024-02	1
PF93619	1034	SUBSTRATE	359	2023-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.020	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.463	≥ 0.200
POSITIVE CONTROL	1.800	> 1.5 CUT-OFF
CV%	7%	≤ 15%

The test has been carried out in accordance with the package insert

TESTED BY: Katia Tanzini

APPROVED BY:

RESPONSIBLE HEAD, Quality Control Reagents

DATE 10.03.2022

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an FDA approved method and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.



CERTIFICATE OF ANALYSIS

KIT: **SARS-CoV-2 IgM**
 LOT: **016**
 DATE OF TEST: **07/03/2022**

Code 91401

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE			FOUND	EXPECTED
UNIFORMITY BETWEEN PLATES				
1st PLATE	OD450 nm		0.548	
	CV%		8%	<20%
2nd PLATE	OD 450nm		0.523	
	CV%		7%	<20%
3rd PLATE	OD 450nm		N/A	
	CV%		N/A	<20%
2. BULK CONTROL date: 24/02/2022				
A) Average OD of Cut Off Control	OD 450 nm		0.564	≥ 0.200
B) Index of Negative and Positive Sera			accepted	According to specification
C) Sensitivity with working calibrators			accepted	According to specification
3. FINAL CONTROL date: 07/03/2022				
A) Blank	OD 450 nm		0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm		0.020	< 0,6xCut Off
C) Average OD of Cut Off Control	OD 450 nm		0.463	≥ 0.200
D) Average OD of Positive Control	OD 450 nm		1.800	> 1,5 x Cut Off
E) HOMOGENEITY OF CUT-OFF				
	No.		6	
	OD 450 nm		0.508	
	CV%		7%	≤15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 08/03/2022

Signed: *Alioudi*
 Released: Q.C.Manager