

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



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

QUALITY CONTROL CERTIFICATE

KIT NAME HERPES SIMPLEX 1 IgG RECOMBINANT

Code	91023		
LOT.NO	041-A	2024-02	2022-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93021	E8630	MICROPLATE	053	2024-03	1
PF93523	D8630	CONJUGATE	038-1	2024-02	1
PF93910	1036	NEGATIVE CONTROL	174-2	2024-02	1
PF93823	B8630	POSITIVE CONTROL	038-1	2024-05	1
PF91823	C8630	CUT OFF CONTROL	038-1	2024-05	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1
PF30029	1031	DILUENT 3	050-1	2024-05	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISKO	STOP SOLUTION	215-5	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.045	<0,6 Cut Off
CUT OFF CONTROL	0.341	≥ 0.200
POSITIVE CONTROL	2.183	>1,5 Cut Off
CV%	14%	≤ 15%

*Evaluatin of the method according to the package inset in the attached document
This batch has been manufactured and checked according to quality requirements.
Hereby, it is released to distribution.*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 05.05.2023

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 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: **HERPES SIMPLEX 1 IgG RECOMBINANT**
 LOT: **041**
 DATE OF TEST: **23/11/2022**

Code 91023
 Code 91182

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.139	
	CV%	8%	<20%
2nd PLATE	OD 450nm	2.069	
	CV%	5%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.512	
	CV%	8%	≤15%
2. BULK CONTROL date: 09/11/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.367	≥ 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: 23/11/2022			
A) Blank	OD 450 nm	0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.038	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.480	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.474	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.526	
	CV%	14%	≤15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **23/11/2022**

Signed: 
 Released: Q.C.Manager