

DIESSA 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 ENZYWELL HERPES SIMPLEX 1 + 2 IgG

Code	91020		
LOT.NO	228-C	2024-09	2023-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93120	006340	MICROPLATE	233	2024-10	1
PF93503	006350	CONJUGATE	264	2024-11	1
PF93910	1036	NEGATIVE CONTROL	176-1	2024-11	1
PF92000	006370	POSITIVE CONTROL	241	2025-02	1
PF91820	006200	CUT OFF CONTROL	238	2025-02	1
PF93619	1034	SUBSTRATE-HS	376-1	2024-10	1
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISKO	STOP SOLUTION	218	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.006	≤ 0,6 Cut Off
CUT OFF CONTROL	0.455	≥ 0.200
POSITIVE CONTROL	1.849	≥ 1,5 Cut Off
CV %	4%	≤ 15%

*Evaluation of the method according to the package insert 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: 19.09.23

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.

IO 09- 003-V



CODE 91020
CODE 91174

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1+2 IgG
LOT. 228
DATE OF TEST 14/09/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.322	
	CV%	6%	< 20%
2nd PLATE	OD 450 nm	1.224	
	CV%	4%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.223	
	CV%	7%	< 15%
2. BULK CONTROL date: <u>08/09/2023</u>			
A) Average OD of Cut Off Control	OD 450 nm	0.569	≥ 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: <u>14/09/2023</u>			
A) Blank	OD 450 nm	0.049	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.006	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.455	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.849	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.504	
	CV%	4%	≤ 15%
F) PRECISION OF FILLING PROCESS			

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 14/09/2023

Signed: 
Released: Q.C.Manager