

DIESSE DIAGNOSTICA SENESE SpA
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1+2 IgG

Code	91020		
LOT.NO	231	 2025-09	 2024-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93120	006340	MICROPLATE	239	2025-09	1
PF93503	006350	CONJUGATE	268	2025-09	1
PF93910	1036	NEGATIVE CONTROL	180-1	2025-11	1
PF92000	006370	POSITIVE CONTROL	245	2025-12	1
PF91820	006200	CUT OFF CONTROL	242	2025-12	1
PF93619	1034	SUBSTRATE-HS	387	2025-09	1
PF93611	009660	DILUENT 2	234	2025-12	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISK0	STOP SOLUTION	220	2026-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.001	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.423	≥ 0.200
POSITIVE CONTROL	1.946	$\geq 1,5$ Cut Off
CV %	6%	$\leq 15\%$

Evaluation 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:

28.06.2024

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. 231

DATE OF TEST 26/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND

OD 450 nm 2.230

CV% 5%

EXPECTED

< 20%

2nd PLATE

OD 450 nm 2.229

CV% 4%

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450 nm 2.139

CV% 8%

< 15%

2. BULK CONTROL date: 20/06/2024

A) Average OD of Cut Off Control

OD 450 nm 0.491

≥ 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: 26/06/2024

A) Blank

OD 450 nm 0.048

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.001

≤ 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.423

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 1.946

≥ 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No. 6

OD 450 nm 0.471

CV% 6%

≤ 15%

F) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 26.06.2024

Signed:

Released: Q.C.Manager