

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

Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 + 2 IgG

Code 91020

LOT.NO 230-D



2025-04



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93120	006340	MICROPLATE	237	2025-06	1
PF93503	006350	CONJUGATE	266-1	2025-04	1
PF93910	1036	NEGATIVE CONTROL	178-1	2025-05	1
PF92000	006370	POSITIVE CONTROL	243-1	2025-07	1
PF91820	006200	CUT OFF CONTROL	240-1	2025-07	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.004	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.503	≥ 0.200
POSITIVE CONTROL	2.402	$\geq 1,5$ Cut Off
CV %	8%	$\leq 15\%$

*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:

05.06.2024

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. 230
DATE OF TEST 17/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.067	
	CV%	4%	< 20%
2nd PLATE	OD 450 nm	2.110	
	CV%	6%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.996	
	CV%	4%	< 15%
2. BULK CONTROL date: 09/01/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.472	≥ 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: 17/01/2024			
A) Blank	OD 450 nm	0.050	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.004	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.503	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.402	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.552	
	CV%	8%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 17.1.2024

Signed:

Released: Q.C.Manager