

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 SIMPLEX1 + 2 IgM

Code 91021

LOT.NO 325-B



2024-05



2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006190	MICROPLATE	667	2024-05	1
PF91520	006180	CONJUGATE	245-1	2024-05	1
PF93900/HSV	C4940	NEGATIVE CONTROL	783-1	2024-08	1
PF92022	005140	POSITIVE CONTROL	224-1	2024-08	1
PF91821	006150	CUT OFF CONTROL	237-1	2024-08	1
PF91621	006170	ANTIGEN	222	2026-02	6
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.114	< 0,6 Cut Off
CUT OFF CONTROL	0.490	≥ 0.200
POSITIVE CONTROL	1.993	> 1,5 Cut Off
CV %	7%	≤ 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: 04.05.23

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- 004-V



CODE 91021
CODE 91175

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	HERPES SIMPLEX 1+2 IgM
LOT.	325
DATE OF TEST	27/03/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.176 CV% 5%	< 20%
2nd PLATE	OD 450 nm 1.869 CV% 6%	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450 nm 1.769 CV% 8%	< 15%
2. BULK CONTROL date: 13/03/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.642	≥ 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: 27/03/2023		
A) Blank	OD 450 nm 0.037	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.123	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.485	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.105	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 7 OD 450 nm 0.522 CV% 9%	≤ 15%
F) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED
Date: 27.03.23

Signed:
Released: Q.C.Manager