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 ENZYWELL HERPES SIMPLEX 1 + 2 IgM

Code	91021				
LOT.NO	325-D		2024-05		2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006190	MICROPLATE	667	2024-05	1
PF91520	006180	CONJUGATE	245-2	2024-05	1
PF93900/HSV	C4940	NEGATIVE CONTROL	783-2	2024-08	1
PF92022	005140	POSITIVE CONTROL	224-2	2024-08	1
PF91821	006150	CUT OFF CONTROL	237-2	2024-08	1
PF91621	006170	ANTIGEN	222	2026-02	6
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	457-1	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1
PF93619	1034	SUBSTRATE-HS	375	2024-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.093	< 0,6 Cut Off
CUT OFF CONTROL	0.410	≥ 0.200
POSITIVE CONTROL	1.823	> 1,5 Cut Off
CV %	9%	≤ 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: 08.06.23

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

DIESSE

CODE 91021
CODE 91175

QUALITY CONTROL CERTIFICATE
Annex: Method Evalution

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

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND		EXPECTED
1. SOLID PHASE				
	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			

[X] SATISFACTORY [ ] UNSATISFACTORY

FINAL RESULT: ACCEPTED
Date: 27.03.23

Signed:
Released: Q.C.Manager