

DIESSE DIAGNOSTICA SENESE SpA
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 + 2 IgM

Code 91021

LOT.NO 327



2025-07



2024-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006190	MICROPLATE	675	2025-07	1
PF91520	006180	CONJUGATE	247	2025-07	1
PF93900/HSV	C4940	NEGATIVE CONTROL	831	2025-12	1
PF92022	005140	POSITIVE CONTROL	226	2025-10	1
PF91821	006150	CUT OFF CONTROL	240	2025-10	1
PF91621	006170	ANTIGEN	224	2026-10	6
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISK0	STOP SOLUTION	220	2026-03	1
PF93619	1034	SUBSTRATE-HS	387	2025-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.132	< 0,6 Cut Off
CUT OFF CONTROL	0.359	≥ 0.200
POSITIVE CONTROL	1.369	> 1,5 Cut Off
CV %	10%	≤ 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: 27.06.2024

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- 004-V



CODE 91021

CODE 91175

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1+2 IgM
LOT. 327
DATE OF TEST 24/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.041	
	CV%	4%	< 20%
2nd PLATE	OD 450 nm	2.155	
	CV%	13%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.851	
	CV%	8%	< 15%
2. BULK CONTROL date: 17/06/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.436	≥ 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: 24/06/2024			
A) Blank	OD 450 nm	0.048	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.132	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.359	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.369	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	5	
	OD 450 nm	0.445	
	CV%	10%	≤ 15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 26.06.2024

Signed: 
Released: Q.C. Manager