

DIESSE DIAGNOSTICA SENESE SpA
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX1 IgM

Code 91028

LOT.NO 242-D



2025-04



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007200	MICROPLATE	674	2025-05	1
PF93925	007190	CUT OFF CONTROL	221-3	2025-07	1
PF93900/HSV	C5020	NEGATIVE CONTROL	830	2025-12	1
PF93923	007220	POSITIVE CONTROL	209-3	2025-07	1
PF91721	007230	ANTIGEN	221	2026-09	6
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	387	2025-09	1
PF30055	007180	CONJUGATE	228-3	2025-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.173	< 0,6 Cut Off
CUT OFF CONTROL	0.484	≥ 0.200
POSITIVE CONTROL	1.030	> 1,5 Cut Off
CV %	12%	≤ 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: 26.06.2024

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- 005-V



CODE 91028

CODE 91186

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1 IgM

LOT. 242

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	3.021	
	CV%	2%	< 20%
2nd PLATE	OD 450 nm	2.794	
	CV%	9%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	3.057	
	CV%	5%	< 15%
2. BULK CONTROL date: 19/01/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.483	≥ 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	0.173	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.484	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.030	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.532	
	CV%	12%	≤ 15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 25.06.2024

Signed:

Released: Q.C.Manager