

DIESSE DIAGNOSTICA SENESE SpA
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code 91025

LOT.NO 239



2025-07



2024-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007250	MICROPLATE	676	2025-11	1
PF93900/HSV	C4960	NEGATIVE CONTROL	827-1	2025-12	1
PF92355	007280	POSITIVE CONTROL	210-1	2025-12	1
PF30056	011560	CONJUGATE	229-1	2025-09	1
PF91722	007300	ANTIGEN	228	2027-06	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
PF30057	011570	CUT OFF CONTROL	223	2025-12	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.106	< 0,6 Cut Off
CUT OFF CONTROL	0.480	≥ 0.200
POSITIVE CONTROL	2.671	> 1,5 Cut Off
CV %	8%	≤ 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: 21.06.2024

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 91025
CODE 91187

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 2 IgM
LOT. 239
DATE OF TEST 20/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.454	
	CV%	10%	< 20%
2nd PLATE	OD 450 nm	2.644	
	CV%	8%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	2.617	
	CV%	11%	< 15%
2. BULK CONTROL date: 18/06/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.510	≥ 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: 20/06/2024			
A) Blank	OD 450 nm	0.048	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.106	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.480	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.671	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.528	
	CV%	8%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20.06.2024

Signed:

Released: Q.C.Manager