

DIESSE DIAGNOSTICA SENESE SpA
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code	91025		
LOT.NO	238	2025-07	2024-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007250	MICROPLATE	676	2025-11	1
PF93900/HSV	C4960	NEGATIVE CONTROL	827	2025-12	1
PF92355	007280	POSITIVE CONTROL	210	2025-12	1
PF30056	011560	CONJUGATE	229	2025-09	1
PF91722	007300	ANTIGEN	227	2026-11	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	222	2025-12	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.149	< 0,6 Cut Off
CUT OFF CONTROL	0.449	≥ 0.200
POSITIVE CONTROL	1.462	> 1,5 Cut Off
CV %	8%	≤ 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: 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. 238
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 0.432	≥ 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 0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.149	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.449	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.462	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF		
	No. 6 OD 450 nm 0.495 CV% 8%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED
Date: 20.06.2024

Signed:
Released: Q.C. Manager