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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX1 IgG

Code 91027

LOT.NO 223



2024-04



2023-02

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93121	007320	MICROPLATE	228	2024-04	1
PF93499	005400	CONJUGATE	263	2024-05	1
PF93910	1036	NEGATIVE CONTROL	176-1	2024-11	1
PF91999	007760	POSITIVE CONTROL	240	2024-08	1
PF91819	007310	CUT OFF CONTROL	237	2024-08	1
PF93619	1034	SUBSTRATE-HS	375-1	2024-09	1
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISK0	STOP SOLUTION	218	2025-06	1
PF91082/G	007740	SORBENT 2	129	2026-01	6

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.013	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.341	≥ 0.200
POSITIVE CONTROL	1.504	$\geq 1,5$ Cut Off
CV %	5%	$\leq 15\%$

Evaluation of the method according to the package insert 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: 23.08.2023

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- 003-V



CODE 91027

CODE 91184

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1 IgG

LOT. 223

DATE OF TEST 12/07/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	2.211
	CV%	3% < 20%
2nd PLATE	OD 450 nm	N/A
	CV%	N/A < 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm	3.035
	CV%	5% < 15%
2. BULK CONTROL date: 15/02/2023		
A) Average OD of Cut Off Control	OD 450 nm	0.367 ≥ 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: 05/07/2023		
A) Blank	OD 450 nm	0.044 ≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.013 ≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.341 ≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.504 ≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6
	OD 450 nm	0.386
	CV%	5% ≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 12/07/2023

Signed:

Released: Q.C.Manager

