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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME HERPES SIMPLEX 1 IgG RECOMBINANT

Code 91023

LOT.NO 043



2025-01



2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93021	E8630	MICROPLATE	054	2025-01	1
PF93523	D8630	CONJUGATE	040	2025-02	1
PF93910	1036	NEGATIVE CONTROL	177-2	2025-03	1
PF93823	B8630	POSITIVE CONTROL	040	2025-05	1
PF91823	C8630	CUT OFF CONTROL	040	2025-05	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF30029	1031	DILUENT 3	053	2025-05	1
PF93603	1035	WASHING BUFFER 10x	464	2025-04	1
PF93602	1032/RISK0	STOP SOLUTION	218-5	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.016	<0,6 Cut Off
CUT OFF CONTROL	0.370	≥ 0.200
POSITIVE CONTROL	2.111	>1,5 Cut Off
CV%	2%	≤ 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:

16.11.2023

WARNING: POTENTIAL BIOHAZARDOUS MATERIALI

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- 275-V



CODE 91023
CODE 91182

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1 IgG RECOMBINANT
LOT. 043
DATE OF TEST 13/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.428	
	CV%	19,5%	< 20%
2nd PLATE	OD 450 nm	1.354	
	CV%	16%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.407	
	CV%	10%	<15%
2. BULK CONTROL date:08/11/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.403	≥ 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:13/11/2023			
A) Blank	OD 450 nm	0.048	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.016	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.370	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.111	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.417	
	CV%	2%	≤15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 13.11.2023

Signed:

Released: Q.C.Manager