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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgG RECOMBINANT

Code 91029

LOT.NO 044



2025-02



2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93029	E8640	MICROPLATE	042	2025-02	1
PF93529	D8640	CONJUGATE	042	2025-02	1
PF93910	1036	NEGATIVE CONTROL	177-2	2025-03	1
PF93829	B8640	POSITIVE CONTROL	041	2025-05	1
PF91829	C8640	CUT OFF CONTROL	041	2025-05	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF30029	1031	DILUENT 3	054	2025-05	1
PF93603	1035	WASHING BUFFER 10x	466	2025-04	1
PF93602	1032/RISKO	STOP SOLUTION	218-5	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.003	<0,6 Cut Off
CUT OFF CONTROL	0.384	≥ 0.200
POSITIVE CONTROL	1.095	>1,5 Cut Off
CV%	6%	≤ 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:

17.11.2023

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 - 276-V



CODE 91029

CODE 91183

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 2 IgG RECOMBINANT
LOT. 044
DATE OF TEST 15/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	0.762	
	CV%	17,8%	< 20%
2nd PLATE	OD 450 nm	n/a	
	CV%	n/a	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	0.891	
	CV%	8%	<15%
2. BULK CONTROL date: 10/11/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.563	≥ 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: 15/11/2023			
A) Blank	OD 450 nm	0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.003	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.384	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.095	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.429	
	CV%	6%	≤15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT:

Date: 15.11.2023

Signed:

Released: Q.C.Manager