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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 043



2024-05



2023-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93029	E8640	MICROPLATE	041	2024-05	1
PF93529	D8640	CONJUGATE	041	2024-09	1
PF93910	1036	NEGATIVE CONTROL	176-1	2024-11	1
PF93829	B8640	POSITIVE CONTROL	040	2024-12	1
PF91829	C8640	CUT OFF CONTROL	040	2024-12	1
PF93619	1034	SUBSTRATE-HS	375-1	2024-09	1
PF30029	1031	DILUENT 3	052	2024-12	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISKO	STOP SOLUTION	218	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.009	<0,6 Cut Off
CUT OFF CONTROL	0.514	≥ 0.200
POSITIVE CONTROL	1.260	>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: 08/08/2023

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 - 276-V



CODE 91029

CODE 91183

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 2 IgG RECOMBINANT

LOT. 043

DATE OF TEST 13/07/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	854	
	CV%	11%	< 20%
2nd PLATE	OD 450 nm	N/A	
	CV%	N/A	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	963	
	CV%	11%	<15%
2. BULK CONTROL date: 04/07/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.522	≥ 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: 11/07/2023			
A) Blank	OD 450 nm	0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.009	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.514	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.260	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	6	
	OD 450 nm	0.559	
	CV%	8%	≤15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date:

Signed:

Released: Q.C.Manager