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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgG RECOMBINANT

Code	91029		
LOT.NO 042-A	2024-02	2022-11	

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93029	E8640	MICROPLATE	040	2024-04	1
PF93529	D8640	CONJUGATE	040	2024-02	1
PF93910	1036	NEGATIVE CONTROL	174-2	2024-02	1
PF93829	B8640	POSITIVE CONTROL	039	2024-05	1
PF91829	C8640	CUT-OFF CONTROL	039	2024-05	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1
PF30029	1031	DILUENT 3	051	2024-05	1
PF93603	1035	WASHING BUFFER 10x	452	2024-02	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.014	<0,6 Cut Off
CUT-OFF CONTROL	0.464	≥ 0.200
POSITIVE CONTROL	1.166	>1,5 Cut Off
CV%	5%	≤ 15%

The test has been carried out in accordance with the package insert

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 25/11/2022

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 FDA approved method 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.



CERTIFICATE OF ANALYSIS

KIT: **HERPES SIMPLEX 2 IgG RECOMBINANT**
 LOT: **042**
 DATE OF TEST: **22/11/2022**

Code 91029
 Code 91183

METHOD: ACCORDING TO THE PACKAGE INSERT

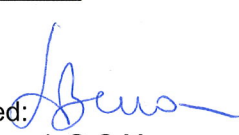
		FOUND	EXPECTED
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
	OD450 nm	1.550	
	CV%	4%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.568	
	CV%	6%	<15%
2. BULK CONTROL date: 10/11/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.382	≥ 0.200
B) Index of Negative and Positive Sera		accepted	According to specification
C) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 22/11/2022			
A) Blank	OD 450 nm	0.043	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.014	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.464	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.166	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF			
	No.	6	
	OD 450 nm	0.507	
	CV%	5%	≤15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **22.11.2022**

Signed: 
 Released: Q.C.Manager