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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-D

 2024-02

 2022-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93029	E8640	MICROPLATE	040	2024-04	1
PF93529	D8640	CONJUGATE	040-3	2024-02	1
PF93910	1036	NEGATIVE CONTROL	174-2	2024-02	1
PF93829	B8640	POSITIVE CONTROL	039-3	2024-05	1
PF91829	C8640	CUT OFF CONTROL	039-3	2024-05	1
PF93619	1034	SUBSTRATE-HS	371	2024-06	1
PF30029	1031	DILUENT 3	051-3	2024-05	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.021	<0,6 Cut Off
CUT OFF CONTROL	0.353	≥ 0.200
POSITIVE CONTROL	0.930	>1,5 Cut Off
CV%	6%	≤ 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:

17.05.2023

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.



CERTIFICATE OF ANALYSIS

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

Code 91029
 Code 91183

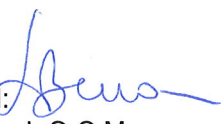
METHOD: ACCORDING TO THE PACKAGE INSERT

		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