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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 040-D	2023-07		2022-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93029	E8640	MICROPLATE	039	2023-09	1
PF93529	D8640	CONJUGATE	038-1	2023-07	1
PF93910	1036	NEGATIVE CONTROL	173-1	2023-11	1
PF93829	B8640	POSITIVE CONTROL	037-1	2023-10	1
PF91829	C8640	CUT-OFF CONTROL	037-1	2023-10	1
PF93619	1034	SUBSTRATE-HS	364	2023-11	1
PF30029	1031	DILUENT 3	046-1	2023-10	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.013	<0,6 Cut Off
CUT-OFF CONTROL	0.462	≥ 0.200
POSITIVE CONTROL	1.259	>1,5 Cut Off
CV%	7%	≤ 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: 30.06.22

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** Code 91029
LOT: **040** Code 91183
DATE OF TEST: **25/05/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND	*EXPECTED*
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
	OD450 nm	**1.580**	
	CV%	**6%**	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	**1.509**	
	CV%	**8%**	<15%
2. BULK CONTROL date: 18/05/2022			
A) Average OD of Cut Off Control	OD 450 nm	**0.487**	≥ 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: 25/05/2022			
A) Blank	OD 450 nm	**0.045**	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	**0.013**	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	**0.462**	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	**1.259**	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF	No.	**6**	
	OD 450 nm	**0.507**	
	CV%	**7%**	≤15%

F) PRECISION OF FILLING PROCESS

[X] SATISFACTORY [ ] UNSATISFACTORY

FINAL RESULT: **ACCEPTED**
Date: 25.05.22

Signed:
Released: Q.C.Manager