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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 1 IgG

Code	91027		
LOT.NO	221-A	2023-08	2022-07

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93121	007320	MICROPLATE	227	2023-08	1
PF93499	005400	CONJUGATE	258	2023-10	1
PF93910	1036	NEGATIVE CONTROL	174	2024-02	1
PF91999	007760	POSITIVE CONTROL	235	2023-09	1
PF91819	007310	CUT-OFF CONTROL	232	2023-09	1
PF93619	1034	SUBSTRATE-HS	365	2023-11	1
PF93611	009660	DILUENT 2	225	2023-12	1
PF93603	1035	WASHING BUFFER 10x	451-1	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF91082/G	007740	SORBENT 2	128	2025-06	6

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.023	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.459	≥ 0.200
POSITIVE CONTROL	3.177	$\geq 1,5$ CUT-OFF
CV %	3%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 20.08.2022

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 1 IgG**
LOT: 221
DATE OF TEST: 22/08/2022

Code 91027
Code 91184

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.206	
	CV%	4%	≤20%
2nd PLATE	OD 450nm	N/A	
	CV%	N/A	≤20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.965	
	CV%	5%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank			
		0.048	≤0.100
OD 450 nm Negative Control			
		0.023	(≤ 0.6xCut-off)
OD 450 nm Cut-off Control			
		0.459	>0.200
OD 450 nm Positive Control			
		3.177	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA			
Average OD of Negative Sera		accepted	< Cut-off
Average OD of Positive Sera		accepted	> Cut-off

FINAL RESULT: **ACCEPTED**

Date: 22/08/2022

Signed:

Released: Q.C.Manager

Aggiornamento 05/2012