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Sede Legale e Amministrazione
Via Solari, 19 20114 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 + 2 IgG

Code 91020

LOT.NO 224 EXPIRY 2023-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93120	006340	MICROPLATE	231	2023-09	1
PF93503	006350	CONJUGATE	256	2023-06	1
PF93910	1036	NEGATIVE CONTROL	172-1	2023-08	1
PF92000	006370	POSITIVE CONTROL	234	2023-09	1
PF91820	006200	CUT-OFF CONTROL	231	2023-09	1
PF93619	1034	SUBSTRATE-HS	361	2023-07	1
PF93611	009660	DILUENT 2	223	2023-08	1
PF93603	1035	WASHING BUFFER 10x	447-1	2023-08	1
PF93602	1032/RISK0	STOP SOLUTION	214	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.011	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.504	≥ 0.200
POSITIVE CONTROL	2.352	$\geq 1,5$ CUT-OFF
CV %	7%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: (RESPONSIBLE HEAD, Quality Control Reagents)

DATE: 22.04.22

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 1+2 IgG**
 LOT: **224**
 DATE OF TEST: **12/04/2022**

Code 91020
 Code 91142
 Code 91174

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.326	
	CV%	3%	<20%
2nd PLATE	OD 450nm	1.411	
	CV%	4%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.261	
	CV%	5%	≤15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.044	≤0.100
OD 450 nm Negative Control		0.011	(≤0.6xCut-off)
OD 450 nm Cut-off Control		0.504	>0.200
OD 450 nm Positive Control		2.352	(≥1,5 x Cut-off)
B) PANEL OF HUMAN SERA			
Average OD 450nm of Negative Sera		accepted	< Cut-off
Average OD 450nm of Positive Sera		accepted	> Cut-off
C) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.537	
	CV%	7%	≤ 15%
D) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **12.04.2022**

Signed:
 Released: Q.C. Manager

Aggiornamento 05.2012