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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-E EXPIRY 2023-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93120	006340	MICROPLATE	231	2023-09	1
PF93503	006350	CONJUGATE	256-1	2023-06	1
PF93910	1036	NEGATIVE CONTROL	173-1	2023-11	1
PF92000	006370	POSITIVE CONTROL	234-1	2023-09	1
PF91820	006200	CUT-OFF CONTROL	231-1	2023-09	1
PF93619	1034	SUBSTRATE-HS	362-1	2023-09	1
PF93611	009660	DILUENT 2	224	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	0.011	$\leq 0,6$ 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: 24.06.2022

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+2 IgG	Code	91020
LOT:	224	Code	91142
DATE OF TEST:	12/04/2022	Code	91174

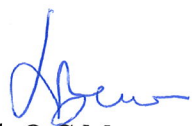
METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
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