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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

Code 91026

LOT.NO 180-B

 2024-04

 2023-02

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93020	006660	MICROPLATE	134	2024-04	1
PF93502	006640	CONJUGATE	155	2024-05	1
PF93910	1036	NEGATIVE CONTROL	176	2024-11	1
PF91629	006680	POSITIVE CONTROL	138	2024-08	1
PF91628	006650	CUT OFF CONTROL	130	2024-08	1
PF93619	1034	SUBSTRATE-HS	375-1	2024-09	1
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISK0	STOP SOLUTION	215-7	2024-08	1
PF91081/G	006670	SORBENT 1	143	2026-01	6

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.006	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.396	≥ 0.200
POSITIVE CONTROL	1.582	$\geq 1,5$ Cut Off
CV%	6%	$\leq 15\%$

*Evaluatin 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:

05.07.2023

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.

IO 09- 008-V



CODE 91026

CODE 91185

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	HERPES SIMPLEX 2 IgG
LOT.	180
DATE OF TEST	21/02/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.490	
	CV% 4%	< 20%
2nd PLATE	OD 450 nm N/A	
	CV% N/A	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.435	
	CV% 5%	< 15%
2. BULK CONTROL date: 15/02/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.408	≥ 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: 21/02/2023		
A) Blank	OD 450 nm 0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.006	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.396	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.582	≥ 1,5Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6	
	OD 450 nm 0.441	
	CV% 6%	≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 21.02.2023

Signed:

Released: Q.C. Manager