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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgG

Code 91026

LOT.NO 181-A



2024-11



2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93020	006660	MICROPLATE	135	2024-11	1
PF93502	006640	CONJUGATE	156	2025-02	1
PF93910	1036	NEGATIVE CONTROL	178	2025-05	1
PF91629	006680	POSITIVE CONTROL	139	2025-05	1
PF91628	006650	CUT OFF CONTROL	131	2025-05	1
PF93619	1034	SUBSTRATE-HS	381	2025-04	1
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	466	2025-04	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF91081/G	006670	SORBENT 1	143	2026-01	6

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.009	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.520	≥ 0.200
POSITIVE CONTROL	1.786	$\geq 1,5$ Cut Off
CV%	2%	$\leq 15\%$

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: 07.12.2023

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. 181
DATE OF TEST 05/12/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.114	
	CV%	6%	< 20%
2nd PLATE	OD 450 nm	N/A	
	CV%	N/A	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.194	
	CV%	5%	< 15%
2. BULK CONTROL date:30/11/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.482	≥ 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:05/12/2023			
A) Blank	OD 450 nm	0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.009	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.520	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.786	≥ 1,5Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	6	
	OD 450 nm	0.567	
	CV%	2%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 05.12.2023

Signed:

Released: Q.C.Manager