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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME HERPES SIMPLEX 1 IgG RECOMBINANT

Code	91023		
LOT.NO	042	2024-09	2023-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93021	E8630	MICROPLATE	053	2024-11	1
PF93523	D8630	CONJUGATE	039	2024-09	1
PF93910	1036	NEGATIVE CONTROL	176-1	2024-11	1
PF93823	B8630	POSITIVE CONTROL	039	2024-12	1
PF91823	C8630	CUT OFF CONTROL	039	2024-12	1
PF93619	1034	SUBSTRATE-HS	376-1	2024-10	1
PF30029	1031	DILUENT 3	052-1	2024-12	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISKO	STOP SOLUTION	218	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.044	<0,6 Cut Off
CUT OFF CONTROL	0.558	≥ 0.200
POSITIVE CONTROL	3.024	>1,5 Cut Off
CV%	12%	≤ 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: 13.09.2023

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- 275-V



CODE 91023

CODE 91182

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1 IgG RECOMBINANT
LOT. 042
DATE OF TEST 11/09/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES
1st PLATE

2nd PLATE

B) UNIFORMITY WITHIN PLATE

FOUND

EXPECTED

OD 450 nm	2.139	
CV%	8%	< 20%
OD 450 nm	2.069	
CV%	5%	< 20%

OD 450nm	1.512	
CV%	8%	<15%

2. BULK CONTROL date: 29/08/2023

- A) Average OD of Cut Off Control
- B) Index of Negative and Positive Sera
- C) Sensitivity with working calibrators

OD 450 nm	0.494	≥ 0.200
accepted	accepted	According to specification

3. FINAL CONTROL date: 11/09/2023

- A) Blank
- B) Average OD of Negative Control
- C) Average OD of Cut Off Control
- D) Average OD of Positive Control

OD 450 nm	0.047	≤ 0.100
OD 450 nm	0.044	< 0,6 Cut Off
OD 450 nm	0.558	≥ 0.200
OD 450 nm	3.024	> 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No.	6	
OD 450 nm	0.605	
CV%	12%	≤15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 12/09/2023

Signed:

Released: Q.C.Manager