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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 1 IgG

Code	91027		
LOT.NO	224-C	2025-06	2024-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93121	007320	MICROPLATE	238	2025-09	1
PF93499	005400	CONJUGATE	267	2025-06	1
PF93910	1036	NEGATIVE CONTROL	179-1	2025-06	1
PF91999	007760	POSITIVE CONTROL	244	2025-09	1
PF91819	007310	CUT OFF CONTROL	241	2025-09	1
PF93619	1034	SUBSTRATE-HS	387	2025-09	1
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1
PF91082/G	007740	SORBENT 2	129	2026-01	6

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.000	≤ 0,6 Cut Off
CUT OFF CONTROL	0.389	≥ 0.200
POSITIVE CONTROL	1.511	≥ 1,5 Cut Off
CV %	9%	≤ 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: 13.06.2024

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- 003-V



CODE 91027

CODE 91184

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1 IgG
LOT. 224
DATE OF TEST 08/04/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.540 CV% 5%	< 20%
2nd PLATE	OD 450 nm N/A CV% N/A	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.515 CV% 5%	< 15%
2. BULK CONTROL date: 03/04/2024		
A) Average OD of Cut Off Control	OD 450 nm 0.466	≥ 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: 08/04/2024		
A) Blank	OD 450 nm 0.053	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.000	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.389	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.511	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.442 CV% 9%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 08/04/2024

Signed:
Released: Q.C. Manager