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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 182



2025-06



2024-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93020	006660	MICROPLATE	136	2025-11	1
PF93502	006640	CONJUGATE	157	2025-08	1
PF93910	1036	NEGATIVE CONTROL	179	2025-06	1
PF91629	006680	POSITIVE CONTROL	140	2025-11	1
PF91628	006650	CUT OFF CONTROL	132	2025-11	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	1
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	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	0.002	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.373	≥ 0.200
POSITIVE CONTROL	1.247	$\geq 1,5$ Cut Off
CV%	8%	$\leq 15\%$

*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:

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. 182
DATE OF TEST 12/06/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.336	
	CV%	6%	< 20%
2nd PLATE	OD 450 nm	N/A	
	CV%	N/A	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.461	
	CV%	6%	< 15%
2. BULK CONTROL date: 06/06/2024			
A) Average OD of Cut Off Control	OD 450 nm	0.421	≥ 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:12/06/2024			
A) Blank	OD 450 nm	0.048	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.002	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.373	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.247	≥ 1,5Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	8	
	OD 450 nm	0.407	
	CV%	8%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 12.06.2024

Signed:

Released: Q.C.Manager