



QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 + 2 IgG

Code	91020		
LOT.NO	229	2025-02	2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93120	006340	MICROPLATE	236	2025-04	1
PF93503	006350	CONJUGATE	265	2025-02	1
PF93910	1036	NEGATIVE CONTROL	177-2	2025-03	1
PF92000	006370	POSITIVE CONTROL	242	2025-05	1
PF91820	006200	CUT OFF CONTROL	239	2025-05	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	464	2025-04	1
PF93602	1032/RISK0	STOP SOLUTION	218-5	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.007	≤ 0,6 Cut Off
CUT OFF CONTROL	0.483	≥ 0.200
POSITIVE CONTROL	2.542	≥ 1,5 Cut Off
CV %	2%	≤ 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: 16.11.2023

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- 003-V



CODE 91020

CODE 91174

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1+2 IgG
LOT. 229
DATE OF TEST 15/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.721	
	CV% 4%	< 20%
2nd PLATE	OD 450 nm n/a	
	CV% n/a	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.820	
	CV% 5%	< 15%
2. BULK CONTROL date: 10/11/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.436	≥ 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: 15/11/2023		
A) Blank	OD 450 nm 0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.007	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.483	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.542	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF		
	No. 6	
	OD 450 nm 0.528	
	CV% 2%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 15.11.2023

Signed: 
Released: Q.C.Manager