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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX1 IgM

Code 91028

LOT.NO 241-B



2025-02



2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007200	MICROPLATE	672	2025-04	1
PF93925	007190	CUT OFF CONTROL	219-1	2025-05	1
PF93900/HSV	C5020	NEGATIVE CONTROL	805-1	2025-05	1
PF93923	007220	POSITIVE CONTROL	207-1	2025-05	1
PF91721	007230	ANTIGEN	221	2026-09	6
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
PF93619	1034	SUBSTRATE-HS	381	2025-04	1
PF30055	007180	CONJUGATE	226-1	2025-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.247	< 0,6 Cut Off
CUT OFF CONTROL	0.501	≥ 0.200
POSITIVE CONTROL	1.650	> 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: 01.12.2023

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- 005-V



CODE 91028

CODE 91186

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 1 IgM
LOT. 241
DATE OF TEST 14/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.445 CV% 16%	< 20%
2nd PLATE	OD 450 nm 1.639 CV% 4%	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.785 CV% 12%	< 15%
2. BULK CONTROL date: 09/11/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.577	≥ 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: 14/11/2023		
A) Blank	OD 450 nm 0.051	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.197	< 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 1.782	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.589 CV% 7%	≤ 15%
F) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 14.11.2023

Signed:

Released: Q.C. Manager