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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code 91025

LOT.NO

237



2025-02



2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007250	MICROPLATE	673	2025-05	1
PF93900/HSV	C4960	NEGATIVE CONTROL	809	2025-05	1
PF92355	007280	POSITIVE CONTROL	208	2025-05	1
PF30056	011560	CONJUGATE	227	2025-02	1
PF91722	007300	ANTIGEN	227	2026-11	6
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	466	2025-04	1
PF93602	1032/RISKO	STOP SOLUTION	218-5	2025-06	1
PF93619	1034	SUBSTRATE-HS	380-1	2025-03	1
PF30057	011570	CUT OFF CONTROL	220	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.173	< 0,6 Cut Off
CUT OFF CONTROL	0.410	≥ 0.200
POSITIVE CONTROL	1.329	> 1,5 Cut Off
CV %	11%	≤ 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: 23.11.23

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 91025

CODE 91187

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT HERPES SIMPLEX 2 IgM

LOT. 237

DATE OF TEST 23/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND		EXPECTED
OD 450 nm	2.715	
CV%	15%	< 20%
OD 450 nm	2.817	
CV%	8%	< 20%

2nd PLATE

B) UNIFORMITY WITHIN PLATE

OD 450 nm	2.707	
CV%	7%	< 15%

2. BULK CONTROL date: 17/11/2023

A) Average OD of Cut Off Control

OD 450 nm	0.417	≥ 0.200
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B) Index of Negative and Positive Sera

accepted According to specification

C) Sensitivity with working calibrators

accepted According to specification

3. FINAL CONTROL date: 23/11/2023

A) Blank

OD 450 nm	0.045	≤ 0.100
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B) Average OD of Negative Control

OD 450 nm	0.173	< 0,6 Cut Off
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C) Average OD of Cut Off Control

OD 450 nm	0.410	≥ 0.200
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D) Average OD of Positive Control

OD 450 nm	1.329	> 1,5 Cut Off
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E) HOMOGENEITY OF CUT OFF

No.	6	
OD 450 nm	0.454	
CV%	11%	$\leq 15\%$

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 23/11/2023

Signed:

Released: Q.C.Manager