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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 239-H



2024-04



2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007200	MICROPLATE	666	2024-04	1
PF93925	007190	CUT OFF CONTROL	214-1	2024-07	1
PF93900/HSV	C5020	NEGATIVE CONTROL	781-1	2024-07	1
PF93923	007220	POSITIVE CONTROL	202-1	2024-07	1
PF91721	007230	ANTIGEN	220	2025-09	6
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISK0	STOP SOLUTION	218	2025-06	1
PF93619	1034	SUBSTRATE-HS	375-1	2024-09	1
PF30055	007180	CONJUGATE	221-1	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.149	< 0,6 Cut Off
CUT OFF CONTROL	0.398	≥ 0.200
POSITIVE CONTROL	1.297	> 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: 23.08.2023

WARNING: POTENTIAL BIOHAZARDOUS MATERIALI

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.	239
DATE OF TEST	17/02/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND

OD 450 nm 1.799

CV% 4%

EXPECTED

< 20%

2nd PLATE

OD 450 nm 1.772

CV% 6%

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450 nm 1.792

CV% 7%

< 15%

2. BULK CONTROL date: 14/02/2023

A) Average OD of Cut Off Control

OD 450 nm 0.424

≥ 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: 17/02/2023

A) Blank

OD 450 nm 0.045

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.206

< 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.458

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 1.532

> 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No. 8

OD 450 nm 0.511

CV% 8%

≤ 15%

F) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20.02.2023

Signed:

Released: Q.C. Manager

