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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 IgM

Code 91028

LOT.NO 239



2024-04



2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007200	MICROPLATE	666	2024-04	1
PF93925	007190	CUT OFF CONTROL	214	2024-07	1
PF93900/HSV	C5020	NEGATIVE CONTROL	781	2024-07	1
PF93923	007220	POSITIVE CONTROL	202	2024-07	1
PF91721	007230	ANTIGEN	220	2025-09	6
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	453	2024-04	1
PF93602	1032/RISK0	STOP SOLUTION	215-1	2024-08	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1
PF30055	007180	CONJUGATE	221	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.206	< 0,6 Cut Off
CUT OFF CONTROL	0.458	≥ 0,200
POSITIVE CONTROL	1.532	> 1,5 Cut Off
CV %	8%	≤ 15%

*Evaluation 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: 21.02.2023

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.	239
DATE OF TEST	17/02/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.799 CV% 4%	< 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