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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 + 2 IgM

Code 91021

LOT.NO 324



2024-04



2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006190	MICROPLATE	666	2024-04	1
PF91520	006180	CONJUGATE	244	2024-04	1
PF93900/HSV	C4940	NEGATIVE CONTROL	780	2024-07	1
PF92022	005140	POSITIVE CONTROL	223	2024-07	1
PF91821	006150	CUT OFF CONTROL	236	2024-07	1
PF91621	006170	ANTIGEN	221	2026-01	6
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	454	2024-05	1
PF93602	1032/RISKO	STOP SOLUTION	215-1	2024-08	1
PF93619	1034	SUBSTRATE-HS	371	2024-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.112	< 0,6 Cut Off
CUT OFF CONTROL	0.554	≥ 0.200
POSITIVE CONTROL	2.147	> 1,5 Cut Off
CV %	12%	≤ 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:

15.03.2023

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- 004-V



CODE 91021
CODE 91175

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	HERPES SIMPLEX 1+2 IgM
LOT.	324
DATE OF TEST	16/02/2023

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: 31/01/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.414	≥ 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: 16/02/2023		
A) Blank	OD 450 nm 0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.112	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.554	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.147	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.599 CV% 12%	≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 17.02.23

Signed:
Released: Q.C. Manager