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DIESSE

Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX1 IgM

Code 91028

LOT.NO 240-A



2024-06



2023-06

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007200	MICROPLATE	668	2024-06	1
PF93925	007190	CUT OFF CONTROL	217	2024-12	1
PF93900/HSV	C5020	NEGATIVE CONTROL	794	2024-12	1
PF93923	007220	POSITIVE CONTROL	205	2024-12	1
PF91721	007230	ANTIGEN	220	2025-09	6
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISK0	STOP SOLUTION	215-7	2024-08	1
PF93619	1034	SUBSTRATE-HS	376-1	2024-10	1
PF30055	007180	CONJUGATE	224	2024-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.214	< 0,6 Cut Off
CUT OFF CONTROL	0.439	≥ 0.200
POSITIVE CONTROL	1.554	> 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: 03.08.2023

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. 240
DATE OF TEST 20/07/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES	1st PLATE	OD 450 nm	2.086
		CV%	7% < 20%
	2nd PLATE	OD 450 nm	1.841
		CV%	5% < 20%
	B) UNIFORMITY WITHIN PLATE		
	OD 450 nm		2.041
2. BULK CONTROL date: 17/07/2023	CV%		8% < 15%
	A) Average OD of Cut Off Control	OD 450 nm	0.535 ≥ 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: 20/07/2023	A) Blank	OD 450 nm	0.044 ≤ 0.100
	B) Average OD of Negative Control	OD 450 nm	0.214 < 0,6 Cut Off
	C) Average OD of Cut Off Control	OD 450 nm	0.439 ≥ 0.200
	D) Average OD of Positive Control	OD 450 nm	1.554 > 1,5 Cut Off
	E) HOMOGENEITY OF CUT OFF		
	No.	8	
	OD 450 nm	0.483	
	CV%	12% $\leq 15\%$	
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 24.07.23

Signed:

Released: Q.C.Manager