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Sede Legale e Amministrazione
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Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgG

Code 91010

LOT.NO 276-B



2024-04



2023-03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93010	006300	MICROPLATE	260	2024-04	1
PF93501	006280	CONJUGATE	223	2024-06	1
PF93910	1036	IgG NEGATIVE CONTROL	175	2024-06	1
PF93811	006110	CALIBRATOR 1	204-2	2024-05	1
PF91810	005900	CALIBRATOR 2	204-2	2024-05	1
PF93813	005910	CALIBRATOR 3	204-2	2024-05	1
PF93814	005920	CALIBRATOR 4	204-2	2024-05	1
PF93815	005930	CALIBRATOR 5	204-2	2024-05	1
PF93619	1034	SUBSTRATE	372	2024-07	1
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1

CONTROLS

EU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.033	$\leq 0,6$ Cut Off
CALIBRATOR 1 5	0.118	< Cut Off
CALIBRATOR 2 10 (Cut Off)	0.392	≥ 0.200
CALIBRATOR 3 50	0.998	
CALIBRATOR 4 100	1.803	
CALIBRATOR 5 200	2.151	≥ 1.500
CV %	4%	$\leq 15\%$

*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:

11.05.2023

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- 001-V



CODE 91010

CODE 91170

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	CYTOMEGALOVIRUS IgG
LOT.	276
DATE OF TEST	07/04/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.244 CV% 5%	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 2.051 CV% 6%	< 15%
2. BULK CONTROL date: 03/04/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.484	≥ 0.200
B) Index of Negative and Positive Sera	accepted	According to specification
C) Sensitivity with working calibrator	accepted	According to specification
3. CONTROL OF COMPLETE KIT		
A) Substrate Blank	OD 450 nm 0.048	≤ 0.100
Calibrator 0 EU/ml	OD 450 nm 0.033	≤ 0,6 Cut Off
Calibrator 5 EU/ml	OD 450 nm 0.118	< Cut Off
Calibrator 10 EU/ml (Cut Off)	OD 450 nm 0.392	≥ 0.200
Calibrator 50 EU/ml	OD 450 nm 0.998	
Calibrator 100 EU/ml	OD 450 nm 1.803	
Calibrator 200 EU/ml	OD 450 nm 2.151	≥ 1.500
B) HOMOGENEITY OF CUT-OFF	No. 12 OD 450 nm 0.440 CV% 4%	≤ 15%
C) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 07.04.2023

Signed:

Released: Q.C.Manager