

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



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

Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgG

Code	91010		
LOT.NO	278-D	2024-10	2023-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93010	006300	MICROPLATE	262	2024-11	1
PF93501	006280	CONJUGATE	225	2024-12	1
PF93910	1036	IgG NEGATIVE CONTROL	177	2025-03	1
PF93811	006110	CALIBRATOR 1	206	2025-03	1
PF91810	005900	CALIBRATOR 2	206	2025-03	1
PF93813	005910	CALIBRATOR 3	206	2025-03	1
PF93814	005920	CALIBRATOR 4	206	2025-03	1
PF93815	005930	CALIBRATOR 5	206	2025-03	1
PF93619	1034	SUBSTRATE	376-2	2024-10	1
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISKO	STOP SOLUTION	218	2025-06	1

CONTROLS

EU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.018	$\leq 0,6$ Cut Off
CALIBRATOR 1 5	0.184	< Cut Off
CALIBRATOR 2 10 (Cut Off)	0.516	≥ 0.200
CALIBRATOR 3 50	1.050	
CALIBRATOR 4 100	1.800	
CALIBRATOR 5 200	2.402	≥ 1.500
CV %	6%	$\leq 15\%$

*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: 05.10.2023

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. 278
DATE OF TEST 28/09/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	2.143	
	CV%	5%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.995	< 15%
	CV%	11%	
2. BULK CONTROL date: 15/09/2023			
A) Average OD of Cut Off Calibrator	OD 450 nm	0.522	≥ 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	0.059	≤ 0.100
Calibrator 0 EU/ml	OD 450 nm	0.018	≤ 0,6 Cut Off
Calibrator 5 EU/ml	OD 450 nm	0.184	< Cut Off
Calibrator 10 EU/ml (Cut Off)	OD 450 nm	0.516	≥ 0.200
Calibrator 50 EU/ml	OD 450 nm	1.050	
Calibrator 100 EU/ml	OD 450 nm	1.800	
Calibrator 200 EU/ml	OD 450 nm	2.402	≥ 1.500
B) HOMOGENEITY OF CUT-OFF	No.	12	
	OD 450 nm	0.574	
	CV%	6%	≤ 15%
C) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 28.09.2023

Signed:

Released: Q.C. Manager