

DIESSE DIAGNOSTICA SENESE SpA  
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### QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL CYTOMEGALOVIRUS IgG

Code	91010		
LOT.NO	280-F	2025-05	2024-02

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93010	006300	MICROPLATE	266	2025-08	1
PF93501	006280	CONJUGATE	227-3	2025-05	1
PF93910	1036	IgG NEGATIVE CONTROL	180-1	2025-11	1
PF93811	006110	CALIBRATOR 1	208-3	2025-08	1
PF91810	005900	CALIBRATOR 2	208-3	2025-08	1
PF93813	005910	CALIBRATOR 3	208-3	2025-08	1
PF93814	005920	CALIBRATOR 4	208-3	2025-08	1
PF93815	005930	CALIBRATOR 5	208-3	2025-08	1
PF93619	1034	SUBSTRATE	383-1	2025-05	1
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	475	2025-11	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1

### CONTROLS

EU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.018	≤ 0,6 Cut Off
CALIBRATOR 1 5	0.153	< Cut Off
CALIBRATOR 2 10 (Cut Off)	0.496	≥ 0.200
CALIBRATOR 3 50	0.937	
CALIBRATOR 4 100	1.698	
CALIBRATOR 5 200	2.615	≥ 1.500
CV %	5%	≤ 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: 21.06.2024

### 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. 280  
DATE OF TEST 29/05/2024

**METHOD: ACCORDING TO THE PACKAGE INSERT**

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	2.452
	CV%	4% < 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm	2.590 < 15%
	CV%	6%
2. BULK CONTROL date: 23/02/2024		
A) Average OD of Cut Off Calibrator	OD 450 nm	0.556 ≥ 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	0.047 ≤ 0.100
Calibrator 0 EU/ml	OD 450 nm	0.020 ≤ 0,6 Cut Off
Calibrator 5 EU/ml	OD 450 nm	0.152 < Cut Off
Calibrator 10 EU/ml (Cut Off)	OD 450 nm	0.511 ≥ 0.200
Calibrator 50 EU/ml	OD 450 nm	0.843
Calibrator 100 EU/ml	OD 450 nm	1.538
Calibrator 200 EU/ml	OD 450 nm	2.314 ≥ 1.500
B) HOMOGENEITY OF CUT-OFF	No.	6
	OD 450 nm	0.559
	CV%	4% ≤ 15%
C) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED  
Date: 05.06.2024

Signed:   
Released: Q.C. Manager