

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

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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgM

Code	91011		
LOT.NO	332-B	2024-06	2023-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	668	2024-06	1
PF30107	006380	CONJUGATE	232-1	2024-07	1
PF93900/CMM	C4870	NEGATIVE CONTROL	792-1	2024-10	1
PF92012	006310	POSITIVE CONTROL	213-1	2024-10	1
PF91811	006400	CUT OFF CONTROL	217-1	2024-10	1
PF91611	007330	ANTIGEN (3 ml)	192	2026-03	6
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISK0	STOP SOLUTION	218	2025-06	1
PF93619	1034	SUBSTRATE-HS	376-1	2024-10	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.138	< 0,6 Cut Off
CUT OFF CONTROL	0.289	≥ 0.200
POSITIVE CONTROL	1.456	> 1,5 Cut Off
CV %	4%	≤ 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:

25.08.2023

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- 002-V



CODE 91011

CODE 91171

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	CYTOMEGALOVIRUS IgM
LOT.	332
DATE OF TEST	08/06/2023

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 CV% 8%	< 15%
2. BULK CONTROL date: 17/05/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.351	≥ 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: 08/06/2023		
A) Blank	OD 450 nm 0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.101	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.325	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.741	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.371 CV% 8%	≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 08.06.2023

Signed:

Released: Q.C. Manager