

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 IgM

Code 91011

LOT.NO 331-C



2024-03



2022-12

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	667	2024-05	1
PF30107	006380	CONJUGATE	231-1	2024-03	1
PF93900/CMM	C4870	NEGATIVE CONTROL	776-1	2024-06	1
PF92012	006310	POSITIVE CONTROL	212-1	2024-06	1
PF91811	006400	CUT OFF CONTROL	216-1	2024-08	1
PF91611	007330	ANTIGEN (3 ml)	191	2025-02	6
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	454	2024-05	1
PF93602	1032/RISKO	STOP SOLUTION	215-4	2024-08	1
PF93619	1034	SUBSTRATE-HS	371	2024-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.129	< 0,6 Cut Off
CUT OFF CONTROL	0.386	≥ 0.200
POSITIVE CONTROL	2.176	> 1,5 Cut Off
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:

05.06.2023

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.	331
DATE OF TEST	20/03/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND

OD 450 nm 2.176

CV% 5%

EXPECTED

< 20%

2nd PLATE

OD 450 nm 1.869

CV% 6%

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450 nm 1.769

CV% 8%

< 15%

2. BULK CONTROL date: 15/03/2023

A) Average OD of Cut Off Control

OD 450 nm 0.346

≥ 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: 20/03/2023

A) Blank

OD 450 nm 0.056

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.134

< 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.435

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 1.931

> 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No. 6

OD 450 nm 0.491

≤ 15%

CV% 10%

F) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 21.03.2023

Signed:

Released: Q.C.Manager