

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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgM

Code	91011
LOT.NO	335
	2025-04
	2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	674	2025-05	1
PF30107	006380	CONJUGATE	235	2025-04	1
PF93900/CMM	C4870	NEGATIVE CONTROL	813	2025-07	1
PF92012	006310	POSITIVE CONTROL	216	2025-07	1
PF91811	006400	CUT OFF CONTROL	220	2025-07	1
PF91611	007330	ANTIGEN (3 ml)	194	2026-09	6
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.127	< 0,6 Cut Off
CUT OFF CONTROL	0.386	≥ 0.200
POSITIVE CONTROL	1.970	> 1,5 Cut Off
CV %	13%	≤ 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:

30.01.2024

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- 002-V



CODE 91011

CODE 91171

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT CYTOMEGALOVIRUS IgM

LOT. 335

DATE OF TEST 25/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

OD 450 nm 3.021
CV% 2%

< 20%

2nd PLATE

OD 450 nm 2.794
CV% 9%

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450 nm 3.057
CV% 5%

< 15%

2. BULK CONTROL date: 16/01/2024

A) Average OD of Cut Off Control

OD 450 nm 0.420

≥ 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: 25/01/2024

A) Blank

OD 450 nm 0.048

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.127

< 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.386

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 1.970

> 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No. 6
OD 450 nm 0.434
CV% 13%

≤ 15%

F) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 25.01.2024

Signed:

Released: Q.C. Manager