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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-C



2025-04



2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	674	2025-05	1
PF30107	006380	CONJUGATE	235-2	2025-04	1
PF93900/CMM	C4870	NEGATIVE CONTROL	813-2	2025-07	1
PF92012	006310	POSITIVE CONTROL	216-2	2025-07	1
PF91811	006400	CUT OFF CONTROL	220-2	2025-07	1
PF91611	007330	ANTIGEN (3 ml)	194	2026-09	6
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.140	< 0,6 Cut Off
CUT OFF CONTROL	0.358	≥ 0.200
POSITIVE CONTROL	1.864	> 1,5 Cut Off
CV %	7%	≤ 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: 31.05.2024

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
accepted
accepted

≥ 0.200

B) Index of Negative and Positive Sera

According to specification

C) Sensitivity with working calibrators

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