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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgM

Code 91011

LOT.NO

334



2025-01



2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	671	2025-03	1
PF30107	006380	CONJUGATE	234	2025-01	1
PF93900/CMM	C4870	NEGATIVE CONTROL	801	2025-04	1
PF92012	006310	POSITIVE CONTROL	215	2025-04	1
PF91811	006400	CUT OFF CONTROL	219	2025-04	1
PF91611	007330	ANTIGEN (3 ml)	194	2026-09	6
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	462	2025-02	1
PF93602	1032/RISKO	STOP SOLUTION	218-1	2025-06	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.121	< 0,6 Cut Off
CUT OFF CONTROL	0.367	≥ 0.200
POSITIVE CONTROL	1.884	> 1,5 Cut Off
CV %	12%	≤ 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: 26.10.2023

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. 334

DATE OF TEST 19/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.129	
	CV%	13%	< 20%
2nd PLATE	OD 450 nm	1.254	
	CV%	5%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.380	
	CV%	10%	< 15%
2. BULK CONTROL date: 12/10/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.361	≥ 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: 19/10/2023			
A) Blank	OD 450 nm	0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.121	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.367	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	1.884	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	5	
	OD 450 nm	0.412	
	CV%	12%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20.10.2023

Signed:

Released: Q.C.Manager