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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgM

Code 91011

LOT.NO 332-D



2024-06



2023-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	668	2024-06	1
PF30107	006380	CONJUGATE	232	2024-07	1
PF93900/CMM	C4870	NEGATIVE CONTROL	792	2024-10	1
PF92012	006310	POSITIVE CONTROL	213	2024-10	1
PF91811	006400	CUT OFF CONTROL	217	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/RISKO	STOP SOLUTION	218	2025-06	1
PF93619	1034	SUBSTRATE-HS	376-1	2024-10	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.101	< 0,6 Cut Off
CUT OFF CONTROL	0.325	≥ 0.200
POSITIVE CONTROL	1.741	> 1,5 Cut Off
CV %	8%	≤ 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: 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

	FOUND		EXPECTED
1. SOLID PHASE			
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