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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	329-C	2023-11	2022-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006390	MICROPLATE	664	2023-12	1
PF30107	006380	CONJUGATE	229	2023-11	1
PF93900/CMM	C4870	NEGATIVE CONTROL	760	2024-02	1
PF92012	006310	POSITIVE CONTROL	210	2024-02	1
PF91811	006400	CUT-OFF CONTROL	213	2024-02	1
PF91611	007330	ANTIGEN (3 mL)	191	2025-02	6
PF93611	009660	DILUENT 2	224	2023-10	1
PF93603	1035	WASHING BUFFER 10x	451-1	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	214-4	2024-02	1
PF93619	1034	SUBSTRATE-HS	364-2	2023-11	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.056	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.368	≥ 0.200
POSITIVE CONTROL	1.839	> 1,5 CUT-OFF
CV %	10%	≤ 15%

The test has been carried out in accordance with the package insert

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 29.04.2022

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 FDA approved method 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.



CERTIFICATE OF ANALYSIS

KIT: **CYTOMEGALOVIRUS IgM** Code 91011
 LOT: 329 91141
 DATE OF TEST: **31/08/2022** 91171

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE			FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES				
1st PLATE	OD450 nm		1.521	
	CV%		12%	<20%
2nd PLATE	OD 450nm		1.529	
	CV%		9%	<20%
B) UNIFORMITY WITHIN PLATE				
	OD 450nm		1.763	
	CV%		12%	≤15%
2. BULK CONTROL date: 25/08/2022				
A) Average OD of Cut Off Control	OD 450 nm		0.398	≥ 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: 31/08/2022				
A) Blank	OD 450 nm		0.057	≤ 0.100
B) Average OD of Negative Control	OD 450 nm		0.056	< 0,6xCut Off
C) Average OD of Cut Off Control	OD 450 nm		0.368	≥ 0.200
D) Average OD of Positive Control	OD 450 nm		1.839	> 1,5 x Cut Off
E) HOMOGENEITY OF CUT-OFF	No.		6	
	OD 450 nm		0.425	
	CV%		10%	≤15%
F) PRECISION OF FILLING PROCESS				

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 31/08/2022

Signed:

Released: Q.C.Manager

Aggiornamento 05.2012