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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CYTOMEGALOVIRUS IgG

Code 91010

LOT.NO 269-E

EXPIRY 2022-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93010	006300	MICROPLATE	252	2022-12	1
PF93501	006280	CONJUGATE	214	2022-09	1
PF93910	1036	IgG NEGATIVE CONTROL	169-1	2022-11	1
PF93811	006110	CALIBRATOR 1	198	2022-12	1
PF91810	005900	CALIBRATOR 2	198	2022-12	1
PF93813	005910	CALIBRATOR 3	198	2022-12	1
PF93814	005920	CALIBRATOR 4	198	2022-12	1
PF93815	005930	CALIBRATOR 5	198	2022-12	1
PF93619	1034	SUBSTRATE	355	2022-12	1
PF93611	009660	DILUENT 2	219	2022-11	1
PF93603	1035	WASHING BUFFER 10x	442-1	2022-12	1
PF93602	1032/RISK0	STOP SOLUTION	210	2023-02	1

CONTROLS

EU/mL	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.050	≤ 0,6 CUT-OFF
CALIBRATOR 1 5	0.219	< CUT-OFF
CALIBRATOR 2 10 (cut-off)	0.593	≥ 0.200
CALIBRATOR 3 50	1.078	
CALIBRATOR 4 100	1.988	
CALIBRATOR 5 200	2.855	≥ 1.500
CV %	3%	≤ 15%

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

TESTED BY: Irene Maccagli *Irene Maccagli*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents *[Signature]*

DATE: 29.09.2021

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 IgG	Code 91010
LOT:	269	Code 91140
DATE OF TEST:	15/07/2021	Code 91170

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	
	CV%	
	1.600	
	6%	≤ 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm	
	CV%	
	1.375	
	5	≤ 15%
2. BULK CONTROL date: 07/07/2021		
A) Average OD of Cut Off Calibrator	OD 450 nm	
	0.549	≥ 0.200
B) Index of Negative and Positive Sera	accepted	According to specification
C) Sensitivity with working calibrators	accepted	According to specification
2. CONTROL OF COMPLETE KIT		
A) Substrate Blank	OD 450 nm	
	0.045	< 0.100
Calibrator 0 EU/ml	OD 450 nm	
	0.050	≤ 0,6xCut-off
Calibrator 5 EU/ml	OD 450 nm	
	0.219	< Cut-off
Calibrator 10 EU/ml (Cut-off)	OD 450 nm	
	0.593	≥ 0.200
Calibrator 50 EU/ml	OD 450 nm	
	1.078	
Calibrator 100 EU/ml	OD 450 nm	
	1.988	
Calibrator 200 EU/ml	OD 450 nm	
	2.855	≥ 1.500
C) HOMOGENEITY OF CUT-OFF		
	No.	
	12	
	OD 450 nm	
	0.656	
	CV%	
	3%	≤ 15%
D) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20/07/2021

Signed:
Released: Q.C.Manager

Aggiornamento 05.2016