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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CMV SCREEN

Code 91013

LOT.NO

359



2025-05



2024/03

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93013	007670	MICROPLATE	340	2025-09	1
PF93513	007660	CONJUGATE	347	2025-07	1
PF93973	007650	CALIBRATOR	335	2025-09	1
PF92013	004990	POSITIVE CONTROL	298	2025-07	1
PF93619	1034	SUBSTRATE	383	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

FOUND RESULTS		EXPECTED RESULTS	
CALIBRATOR	OD	1.267	0.950 - 1.350
CUT OFF	OD	0.760	
POSITIVE CONTROL/CUT OFF		0,20	0,20 - 0,50
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: 12.01.2024

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- 0014-V



CODE 91013
CODE

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT CYTOMEGALOVIRUS SCREEN
LOT. 359
DATE OF TEST 10/04/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD450 nm CV%	1.250 6% All negative <15%
2nd PLATE	OD 450nm CV%	N/A <15%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm CV%	1.204 5% < 15%
2. ALIGNMENT AND GOOD FUNCTION		
A) Average OD of Calibrator	OD 450 nm	1.276 0.950-1.350
B) Negative Sera		
Index Reference/Index Control	OD 450 nm	/
Positive Sera		
Index Reference/Index Control	OD 450 nm	/
C) Sensitivity with secondary standards		
CMS1 Negative borderline	OD 450 nm	1.129 > Cut Off
CMS2 Positive borderline	Index Sample/Cut Off	0,5 0,4-0,9
CMS3 Positive	Index Sample/Cut Off	0,2 <0,3
3. CONTROL OF COMPLETE KIT		
A) Precision of Calibrator	No. OD 450 nm CV%	12 1.267 12% ≤15%
B) Calculation of Cut Off		
Cut Off = OD Calibrator x 0,6		0.760
C) Panel of Human sera		
Average of 8 Negative sera		1.584 According to spec.
Average of 8 Positive sera		0.172 According to spec.
D) OD Positive Control/OD Cut Off		0,20 0,20 - 0,50
E) Precision of filling:		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 11.04.2024

Released: Q.C. Manager