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Sede Legale e Amministrazione
 Via A. Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL CMV SCREEN

Code 91013

LOT.NO 358-A EXPIRY 2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No	EXP	No
PF93013	007670	MICROPLATE	338	2024-02	1
PF93513	007660	CONJUGATE	346	2024-01	1
PF93973	007650	CALIBRATOR	334	2023-11	1
PF92013	004990	POSITIVE CONTROL	297	2024-01	1
PF93619	1034	SUBSTRATE	365	2023-11	1
PF93603	1035	WASHING BUFFER 10x	451-1	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1

CONTROLS

FOUND RESULTS		EXPECTED RESULTS
CALIBRATOR O.D.	0.971	0,950 - 1,350
CUT OFF O.D.	0.583	
POSITIVE CONTROL/CUT OFF	0.4	0.20 - 0.50
CV %	14%	<= 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

19.09.2022

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:	CMV SCREEN	Code	91013
LOT:	358		
DATE OF TEST:	15/09/2022		

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND	EXPECTED
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.247	All negative
	CV%	7%	<15%
2nd PLATE	OD 450nm	N/A	
	CV%	N/A	<15%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.150	
	CV%	12%	< 15%
2. ALIGNMENT AND GOOD FUNCTION			
A) Average OD of Calibrator	OD 450 nm	1.117	0.950-1.350
B) Negative Sera			
Index Reference/Index Control	OD 450 nm	0,9	0,7 - 1,2
Positive Sera			
Index Reference/Index Control	OD 450 nm	2,4	>0.7
C) Sensitivity with secondary standards			
CMS1 Negative borderline	OD 450 nm	0.721	> Cut-off
CMS2 Positive borderline	Index Sample/Cut Off	0,4	0.4-0.9
CMS3 Positive	Index Sample/Cut Off	0,1	<0.3
3. CONTROL OF COMPLETE KIT			
A) Precision of Calibrator	No.	12	
	OD 450 nm	0.971	
	CV%	14%	≤15%
B) Calculation of Cut-off			
Cut-off = OD Calibrator x 0,6		0.583	
C) Panel of Human sera			
Average of 8 Negative sera		1.052	According to spec.
Average of 8 Positive sera		0.153	According to spec.
D) OD Positive Control/OD Cut-off		0,4	0,20 - 0,50
E) Precision of filling:			
	Satisfactory ☒		Unsatisfactory ☐

FINAL RESULT: **ACCEPTED**

Date: 16/09/2022

Signed:
Released: Q.C.Manager