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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR VCA IgG

Code 91055

LOT.NO 118 EXPIRY 2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93070	005380	MICROPLATE	122	2024-01	1
PF93508	005360	CONJUGATE	112	2023-10	1
PF93910	1036	NEGATIVE CONTROL	174	2024-02	1
PF91870	016560	CALIBRATOR 1	104	2024-01	1
PF30076	016570	CALIBRATOR 2	104	2024-01	1
PF92070	016580	CALIBRATOR 3	104	2024-01	1
PF93619	1034	SUBSTRATE-HS	365	2023-11	1
PF93621	006030	DILUENT 10	161	2024-01	1
PF93603	1035	WASHING BUFFER 10x	451-1	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF91083	006840	SORBENT G	091	2024-01	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL (CAL 0)	0.009	$\leq 0,6$ CUT OFF
CUT-OFF CONTROL (CAL 1)	0.328	≥ 0.200
POSITIVE CONTROL (CAL 3)	2.465	≥ 1.000
CALIBRATOR 2	1.528	
CV %	2%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE

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: **EPSTEIN BARR VCA IgG** Code 91055
 LOT: 118
 DATE OF TEST: 14/09/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.026	
	CV%	5%	≤ 20%
B) UNIFORMITY WITHIN PLATES			
	OD450 nm	1.689	
	CV%	8%	≤ 15%
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank		0.048	≤0.100
OD 450 nm Negative Control CALIBRATORE 0		0.009	≤0,6xCut-off
OD 450 nm Cut-off Control CALIBRATORE 1		0.328	≥ 0,200
OD 450 nm CALIBRATORE 2		1.528	
OD 450 nm Positive Control (CALIBRATORE 3)		2.465	≥1.000
B) PANEL OF HUMAN SERA AND INTERNAL STANDARDS			
Results of Negative Sera		accepted	According to spec.
Results of Positive Sera		accepted	"
Resultsof Internal Standards		accepted	"
C) HOMOGENEITY OF CUT-OFF	No.	6	
	OD 450 nm	0.376	
	CV%	2%	≤15%

FINAL RESULT: **ACCEPTED**

Date: 14/09/2022

Signed: 
 Released: Q.C.Manager

Aggiornamento 12.2011