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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 IgM**

Code	91056		
LOT.NO	129	2023-11	2022-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	No
PF93054	007000	MICROPLATE	027	2023-12	1
PF93571	006990	CONJUGATE	124	2023-11	1
PF93910	1036	NEGATIVE CONTROL	174	2024-02	1
PF91871	016590	CALIBRATOR 1	110	2024-02	1
PF30077	016600	CALIBRATOR 2	110	2024-02	1
PF92072	016610	CALIBRATOR 3	110	2024-02	1
PF93619	1034	SUBSTRATE-HS	365-1	2023-11	1
PF93611	009660	DILUENT 2	225	2023-12	1
PF93603	1035	WASHING BUFFER 10x	451-2	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1
PF30253	B5160	SAMPLE SORBENT 10	013	2024-02	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL (CAL 0)	0.004	< 0,6 CUT-OFF
CUT-OFF CONTROL (CAL 1)	0.536	≥ 0.200
POSITIVE CONTROL (CAL 3)	2.119	≥ 1.000
CALIBRATOR 2	1.222	≥ 0.500
CV %	4%	≤ 15%

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

TESTED BY: Silvia Sardelli**APPROVED BY:** (RESPONSIBLE HEAD, Quality Control Reagents)**DATE:** 04.10.2022**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: EPSTEIN BARR VCA IgM Code 91056
 LOT: 129
 DATE OF TEST: 27/09/2022

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
	OD450 nm	1.478	
	CV%	7%	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	/	
	CV%	/	<15%
2. BULK CONTROL date: 14/09/2022			
A) Average OD of Cut Off Calibrator	OD 450 nm	0.537	≥ 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: 27/09/2022			
A) Blank	OD 450 nm	0.051	≤ 0.100
B) Negative Control	OD 450 nm	0.004	< 0,6Cut Off
C) Calibrator 1 (Cut-off)	OD 450 nm	0.536	≥ 0.200
D) Calibrator 2	OD 450 nm	1.222	≥ 0.500
E) Calibrator 3	OD 450 nm	2.119	≥ 1.000
F) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.587	
	CV%	4%	≤15%

G) PRECISION OF FILLING PROCESS

☒ X SATISFACTORY
 ☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 27.09.2022

Signed: 
 Released: Q.C.Manager