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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR VCA IgG

Code 91055

LOT.NO 122-C

 2025-03

 2023-12

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93070	005380	MICROPLATE	127	2025-05	1
PF93508	005360	CONJUGATE	116	2025-03	1
PF93910	1036	NEGATIVE CONTROL	178-1	2025-05	1
PF91870	016560	CALIBRATOR 1	108	2025-06	1
PF30076	016570	CALIBRATOR 2	108	2025-06	1
PF92070	016580	CALIBRATOR 3	108	2025-06	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1
PF93621	006030	DILUENT 10	166	2025-08	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF91083	006840	SORBENT G	095	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL (CAL 0)	0.011	$\leq 0,6$ Cut Off
CUT OFF CONTROL (CAL 1)	0.602	≥ 0.200
POSITIVE CONTROL (CAL 3)	3.431	≥ 1.000
CALIBRATOR 2	2.311	
CV %	3%	$\leq 15\%$

Evaluation of the method according to the package insert 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: 05.06.2024

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- 020-V



CODE 91055

CODE

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT EPSTEIN BARR VCA IgG
LOT: 122
DATE OF TEST 21/12/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND

EXPECTED

OD 450 nm 2.551

CV% 7%

< 20%

2nd PLATE

OD 450 nm n/a

CV% n/a

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450nm 2.708

CV% 7%

<15%

2. BULK CONTROL date: 13/12/2023

A) Average OD of Cut Off Calibrator

OD 450 nm

0.311

≥ 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: 21/12/2023

A) Blank

OD 450 nm

0.050

≤ 0.100

B) Negative Control

OD 450 nm

0.011

≤ 0,6 Cut Off

C) Calibrator 1 (Cut Off)

OD 450 nm

0.602

≥ 0.200

D) Calibrator 2

OD 450 nm

2.311

E) Calibrator 3

OD 450 nm

3.431

≥ 1.000

F) HOMOGENEITY OF CUT OFF

No.

6

OD 450 nm

0.652

CV%

3%

≤ 15%

G) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 21/12/2023

Signed:

Released: Q.C.Manager