

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



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

Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR VCA IgG

Code	91055		
LOT.NO	121-A	 2024-12	 2023-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93070	005380	MICROPLATE	125	2025-01	1
PF93508	005360	CONJUGATE	115	2024-12	1
PF93910	1036	NEGATIVE CONTROL	177	2025-03	1
PF91870	016560	CALIBRATOR 1	107	2025-03	1
PF30076	016570	CALIBRATOR 2	107	2025-03	1
PF92070	016580	CALIBRATOR 3	107	2025-03	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF93621	006030	DILUENT 10	164	2024-12	1
PF93603	1035	WASHING BUFFER 10x	462	2025-02	1
PF93602	1032/RISK0	STOP SOLUTION	218-1	2025-06	1
PF91083	006840	SORBENT C	094	2024-12	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL (CAL 0)	0.055	$\leq 0,6$ Cut Off
CUT OFF CONTROL (CAL 1)	0.415	≥ 0.200
POSITIVE CONTROL (CAL 3)	2.504	≥ 1.000
CALIBRATOR 2	1.598	
CV %	1%	$\leq 15\%$

*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: 25.10.2023

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. 121

DATE OF TEST 19/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND		EXPECTED
OD 450 nm	2.104	
CV%	11%	< 20%

2nd PLATE

OD 450 nm	2.342	
CV%	6%	< 20%

B) UNIFORMITY WITHIN PLATE

OD 450nm	2.467	
CV%	8%	<15%

2. BULK CONTROL date: 22/09/2023

A) Average OD of Cut Off Calibrator

OD 450 nm	0.431	≥ 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: 19/10/2023

A) Blank

OD 450 nm	0.046	≤ 0.100
-----------	-------	---------

B) Negative Control

OD 450 nm	0.055	≤ 0,6 Cut Off
-----------	-------	---------------

C) Calibrator 1 (Cut Off)

OD 450 nm	0.415	≥ 0.200
-----------	-------	---------

D) Calibrator 2

OD 450 nm	1.598	
-----------	-------	--

E) Calibrator 3

OD 450 nm	2.504	≥ 1.000
-----------	-------	---------

F) HOMOGENEITY OF CUT OFF

No.	6	
OD 450 nm	0.461	
CV%	1%	≤ 15%

G) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date:

19/10/2023

Signed:

Released: Q.C.Manager