

## QUALITY CONTROL CERTIFICATE

**KIT NAME ENZYWELL EPSTEIN BARR EBNA IgG**

Code	91057		
LOT.NO	105	 2025-02	 2023-11


### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93071	054800	MICROPLATE	120	2025-03	1
PF93509	005470	CONJUGATE	105	2025-02	1
PF93910	1036	NEGATIVE CONTROL	178	2025-05	1
PF92073	005390	POSITIVE CONTROL	097	2025-05	1
PF91873	005450	CUT OFF CONTROL	097	2025-05	1
PF93619	1034	SUBSTRATE-HS	381	2025-04	1
PF93621	006030	DILUENT 10	165	2025-05	1
PF93603	1035	WASHING BUFFER 10x	466	2025-04	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	0.030	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.558	$\geq 0.200$
POSITIVE CONTROL	1.545	$\geq 1,5$ Cut Off
CV %	7%	$\leq 15\%$

*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: 07.12.2023

### 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- 022-V



CODE 91057  
CODE \_\_\_\_\_

**QUALITY CONTROL CERTIFICATE**  
Annex: Method Evaluation

NAME KIT EPSTEIN BARR EBNA IgG  
LOT. 105  
DATE OF TEST 05/12/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND

EXPECTED

OD 450 nm 1.941

CV% 7%

< 20%

OD 450 nm N/A

CV% N/A

< 20%

2nd PLATE

B) UNIFORMITY WITHIN PLATE

OD 450 nm 2.148

CV% 6%

< 15%

2. BULK CONTROL date: 29/11/2023

A) Average OD of Cut Off Control

B) Index of Negative and Positive Sera

C) Sensitivity with working calibrators

OD 450 nm 0.421  
accepted  
accepted

≥ 0.200  
According to specification  
According to specification

3. FINAL CONTROL date: 05/12/2023

A) Blank

B) Average OD of Negative Control

C) Average OD of Cut Off Control

D) Average OD of Positive Control

OD 450 nm 0.047

OD 450 nm 0.030

OD 450 nm 0.558

OD 450 nm 1.545

≤ 0.100  
≤ 0,6 Cut Off  
≥ 0.200  
≥ 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No. 6

OD 450 nm 0.605

CV% 7%

≤ 15%

F) PRECISION OF FILLING PROCESS

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 05.12.2023

Signed:   
Released: Q.C.Manager