



QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR EBNA IgG

Code	91057		
LOT.NO	103-A	2024-06	2023-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93071	054800	MICROPLATE	118	2024-09	1
PF93509	005470	CONJUGATE	103	2024-07	1
PF93910	1036	NEGATIVE CONTROL	176	2024-11	1
PF92073	005390	POSITIVE CONTROL	095	2024-10	1
PF91873	005450	CUT OFF CONTROL	095	2024-10	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1
PF93621	006030	DILUENT 10	163	2024-06	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1
PF91083	006840	SORBENT C	093	2024-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.000	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.504	≥ 0.200
POSITIVE CONTROL	1.735	$\geq 1,5$ Cut Off
CV %	6%	$\leq 15\%$

*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: 19/05/2023

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 _____

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Annex: Method Evaluation

NAME KIT	EPSTEIN BARR EBNA IgG
LOT.	103
DATE OF TEST	16/05/2023

METHOD: ACCORDING TO THE PACKAGE INSERT


1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.947	
	CV% 2%	< 20%
2nd PLATE	OD 450 nm N/A	
	CV% N/A	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.722	
	CV% 4%	< 15%
2. BULK CONTROL date: 05/05/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.516	≥ 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: 16/05/2023		
A) Blank	OD 450 nm 0.077	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.000	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.504	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 1.735	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6	
	OD 450 nm 0.581	
	CV% 6%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 16.05.2023

Signed: 
Released: Q.C.Manager