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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR EBNA IgG

Code 91057

LOT.NO 107



2025-06



2024-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93071	054800	MICROPLATE	123	2025-11	1
PF93509	005470	CONJUGATE	107	2025-08	1
PF93910	1036	NEGATIVE CONTROL	179	2025-06	1
PF92073	005390	POSITIVE CONTROL	099	2025-11	1
PF91873	005450	CUT OFF CONTROL	099	2025-11	1
PF93619	1034	SUBSTRATE-HS	385	2025-08	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	096	2025-09	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.002	$\leq 0,6$ Cut Off
CUT OFF CONTROL	0.452	≥ 0.200
POSITIVE CONTROL	2.042	$\geq 1,5$ 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:

23/05/2024

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- 022-V



CODE 91057

CODE

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT EPSTEIN BARR EBNA IgG
LOT. 107
DATE OF TEST 22/05/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.026 CV% 4%	< 20%
2nd PLATE	OD 450 nm N/A CV% N/A	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 1.905 CV% 8%	< 15%
2. BULK CONTROL date: 20/05/2024		
A) Average OD of Cut Off Control	OD 450 nm 0.405	≥ 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: 22/05/2024		
A) Blank	OD 450 nm 0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.002	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.452	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.042	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.499 CV% 7%	≤ 15%
F) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 22.05.2024

Signed:

Released: Q.C.Manager