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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR EBNA IgG

Code	91057		
LOT.NO	104-B	2024-12	2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93071	054800	MICROPLATE	120	2025-03	1
PF93509	005470	CONJUGATE	104-1	2025-01	1
PF93910	1036	NEGATIVE CONTROL	177-2	2025-03	1
PF92073	005390	POSITIVE CONTROL	096-1	2025-04	1
PF91873	005450	CUT OFF CONTROL	096-1	2025-04	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1
PF93621	006030	DILUENT 10	164	2024-12	1
PF93603	1035	WASHING BUFFER 10x	464	2025-04	1
PF93602	1032/RISKO	STOP SOLUTION	218-5	2025-06	1
PF91083	006840	SORBENT G	094	2024-12	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.022	≤ 0,6 Cut Off
CUT OFF CONTROL	0.371	≥ 0.200
POSITIVE CONTROL	0.985	≥ 1,5 Cut Off
CV %	11%	≤ 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: 09.11.2023

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. 104
DATE OF TEST 18/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1,941 CV% 7%	< 20%
2nd PLATE	OD 450 nm N/A CV% N/A	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 2,148 CV% 6%	< 15%
2. BULK CONTROL date: 12/10/2023		
A) Average OD of Cut Off Control	OD 450 nm 0,457	≥ 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: 18/10/2023		
A) Blank	OD 450 nm 0,039	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0,014	≤ 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0,396	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 0,988	≥ 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0,434 CV% 8%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED
Date: 18.10.2023

Signed: 
Released: Q.C.Manager