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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-A		2024-12		2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93071	054800	MICROPLATE	120	2025-03	1
PF93509	005470	CONJUGATE	104	2025-01	1
PF93910	1036	NEGATIVE CONTROL	177	2025-03	1
PF92073	005390	POSITIVE CONTROL	096	2025-04	1
PF91873	005450	CUT OFF CONTROL	096	2025-04	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 G	094	2024-12	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.014	≤ 0,6 Cut Off
CUT OFF CONTROL	0.396	≥ 0.200
POSITIVE CONTROL	0.988	≥ 1,5 Cut Off
CV %	8%	≤ 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- 022-V

DIESSE

CODE 91057
CODE

QUALITY CONTROL CERTIFICATE

Annex: Method Evalution

NAME KIT EPSTEIN BARR EBNA IgG
LOT. 104
DATE OF TEST 18/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND		EXPECTED
1. SOLID PHASE				
	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			

[X] SATISFACTORY [ ] UNSATISFACTORY

FINAL RESULT: ACCEPTED
Date: 18.10.623

Signed:
Released: Q.C.Manager