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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgG

Code 91040

LOT.NO 254-C EXPIRY 2023-08

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93040	006290	MICROPLATE	221	2023-08	1
PF93506	006270	CONJUGATE	196	2023-08	1
PF93910	1036	IgG NEGATIVE CONTROL	173-2	2023-11	1
PF91840	005150	CALIBRATOR 1	182	2023-11	1
PF93842	005170	CALIBRATOR 2	182	2023-11	1
PF93843	005180	CALIBRATOR 3	182	2023-11	1
PF93844	005190	CALIBRATOR 4	182	2023-11	1
PF93845	005160	CALIBRATOR 5	182	2023-11	1
PF93619	1034	SUBSTRATE-HS	364	2023-11	1
PF93611	009660	DILUENT 2	224	2023-10	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-3	2024-02	1

CONTROLS

	IU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL	0	0.000	≤ 0,6 CUT-OFF
CALIBRATOR 1	8 (cut-off)	0.337	≥ 0.200
CALIBRATOR 2	20	0.698	
CALIBRATOR 3	50	1.285	
CALIBRATOR 4	100	1.812	
CALIBRATOR 5	200	2.097	≥ 1.500
CV %		4%	≤ 15%

The test has been carried out in accordance with the package insert

TESTED BY: Katia Tanzini

APPROVED BY: *RESPONSIBLE HEAD, Quality Control Reagents*

DATE 25.07.22

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 FDA approved method 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.

DIESSE

CERTIFICATE OF ANALYSIS

KIT: **TOXOPLASMA IgG** Code 91040
LOT: **254** Code 91178
DATE OF TEST: **25/05/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND	*EXPECTED*
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	**1.708**	
	CV%	**3%**	≤20%
2nd PLATE	OD 450nm	**1.497**	
	CV%	**4%**	≤20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	**1.397**	
	CV%	**5%**	≤15%
2. CONTROL OF COMPLETE KIT			
A) Substrate Blank	OD 450 nm	**0.045**	≤0.100
Calibrator 0 IU/ml	OD 450 nm	**0.000**	≤0,6xCut-off
Calibrator 8 IU/ml (Cut-off)	OD 450 nm	**0.337**	≥0,200
Calibrator 20 IU/ml	OD 450 nm	**0.698**	
Calibrator 50 IU/ml	OD 450 nm	**1.285**	
Calibrator 100 IU/ml	OD 450 nm	**1.812**	
Calibrator 200 IU/ml	OD 450 nm	**2.097**	≥1,500
B) PANEL OF HUMAN SERA AND INTERNAL STANDARDS			
Results of Negative sera		**accepted**	According to spec.
Results of Positive sera		**accepted**	According to spec.
Results of Internal standards		**accepted**	According to spec.
C) HOMOGENEITY OF CUT-OFF	No.	**6**	
	OD 450 nm	**0.404**	
	CV%	**4%**	≤15%

D) PRECISION OF FILLING PROCESS

[X] SATISFACTORY [ ] UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: 25.05.22

Signed:

Released: Q.C.Manager

Aggiornamento 05/2012