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Sede Legale e Amministrazione  
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### QUALITY CONTROL CERTIFICATE

**KIT NAME** ENZYWELL TOXOPLASMA IgG

Code	91040		
LOT.NO	257	2024-09	2023-06

### REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93040	006290	MICROPLATE	223	2024-11	1
PF93506	006270	CONJUGATE	199	2024-09	1
PF93910	1036	IgG NEGATIVE CONTROL	176	2024-11	1
PF91840	005150	CALIBRATOR 1	186	2024-12	1
PF93842	005170	CALIBRATOR 2	186	2024-12	1
PF93843	005180	CALIBRATOR 3	186	2024-12	1
PF93844	005190	CALIBRATOR 4	186	2024-12	1
PF93845	005160	CALIBRATOR 5	186	2024-12	1
PF93619	1034	SUBSTRATE-HS	376-2	2024-10	1
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	459	2024-10	1
PF93602	1032/RISKO	STOP SOLUTION	218	2025-06	1

### CONTROLS

IU/ml	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.000	≤ 0,6 Cut Off
CALIBRATOR 1 8 (Cut Off)	0.494	≥ 0.200
CALIBRATOR 2 20	0.907	
CALIBRATOR 3 50	1.594	
CALIBRATOR 4 100	1.870	
CALIBRATOR 5 200	2.816	≥ 1.500
CV %	4%	≤ 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: 27.09.2023

### 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 - 012-V



CODE 91040  
CODE 91178

## QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT TOXOPLASMA IgG  
LOT. 257  
DATE OF TEST 20/09/2023

### METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD450 nm	2.484
	CV%	4%
2nd PLATE	OD 450nm	2.179
	CV%	5%
B) UNIFORMITY WITHIN PLATE		
	OD 450nm	2.447
	CV%	5%
2. BULK CONTROL date: 06/09/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm	0.648
B) Index of Negative and Positive Sera		accepted
C) Sensitivity with working calibrators		accepted
3. CONTROL OF COMPLETE KIT date: 20/09/2023		
A) Substrate Blank	OD 450 nm	0.049
Calibrator 0 IU/ml	OD 450 nm	0.000
Calibrator 8 IU/ml (Cut Off)	OD 450 nm	0.494
Calibrator 20 IU/ml	OD 450 nm	0.907
Calibrator 50 IU/ml	OD 450 nm	1.594
Calibrator 100 IU/ml	OD 450 nm	1.870
Calibrator 200 IU/ml	OD 450 nm	2.816
B) HOMOGENEITY OF CUT OFF	No.	6
	OD 450 nm	0.543
	CV%	4%
C) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20.09.2023

Signed:   
Released: Q.C. Manager