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Sede Legale e Amministrazione
 Via A. Solari, 19 20144 Milano - Italy

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgA

Code 91043

LOT.NO 084 EXPIRY 2024-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93040/A	007810	MICROPLATE	223	2024-11	1
PF93549	007800	CONJUGATE	082	2025-05	1
PF92043	007780	POSITIVE CONTROL	077	2025-08	1
PF93910	1036/A	NEGATIVE CONTROL IgA	179-1	2025-06	1
PF91843	007790	CUT OFF CONTROL	080	2025-08	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1
PF93703	008060	DILUENT 50x per IgA	077	2025-04	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.007	$\leq 0,6$ CUT-OFF
CUT-OFF CONTROL	0.386	≥ 0.200
POSITIVE CONTROL	1.354	$\geq 1,5$ CUT-OFF
CV %	6%	$\leq 15\%$

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

TESTED BY: Katia Tanzini

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE 18.03.2024

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 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.



CERTIFICATE OF ANALYSIS

KIT: **TOXOPLASMA IgA** Code 91043
 LOT: **084**
 DATE OF TEST: **15/03/2024**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	2.484	
	CV%	4%	$\leq 20\%$
2nd PLATE	OD 450nm	2.179	
	CV%	5%	$\leq 20\%$
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	2.447	
	CV%	5%	$\leq 15\%$
2. CONTROL OF COMPLETE KIT			
A) OD 450 nm Substrate Blank			
		0.054	≤ 0.100
OD 450 nm Negative Control			
		0.007	$(\leq 0.6 \times \text{Cut-off})$
OD 450 nm Cut-off Control			
		0.386	≥ 0.200
OD 450 nm Positive Control			
		1.354	$(\geq 1,5 \times \text{Cut-off})$
B) PANEL OF HUMAN SERA			
Average OD of Negative Sera		accepted	< Cut-off
Average OD of Positive Sera		accepted	> Cut-off
C) HOMOGENEITY OF CUT-OFF			
	No.	6	
	OD 450 nm	0.440	
	CV%	6%	$\leq 15\%$

FINAL RESULT: **ACCEPTED**

Date: **15.03.2024**

Signed: 
 Released: Q.C.Manager