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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgM

Code 91041

LOT.NO 315-C



2023-11



2022-09

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006330	MICROPLATE	664	2023-12	1
PF91540	006320	CONJUGATE	220-2	2023-11	1
PF93900/TXM	C5100	NEGATIVE CONTROL	761-2	2024-02	1
PF92042	005370	POSITIVE CONTROL	201-2	2024-02	1
PF91841	005120	CUT-OFF CONTROL	200-2	2024-02	1
PF91641	005130	ANTIGEN (3,0 mL)	204	2025-02	6
PF93611	009660	DILUENT 2	226	2024-04	1
PF93603	1035	WASHING BUFFER 10x	453	2024-04	1
PF93602	1032/RISK0	STOP SOLUTION	215-4	2024-08	1
PF93619	1034	SUBSTRATE-HS	368	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.134	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.287	≥ 0.200
POSITIVE CONTROL	2.085	> 1,5 CUT-OFF
CV %	13%	≤ 15%

*Evaluation 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:

19.06.2023

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.



CERTIFICATE OF ANALYSIS

KIT: **TOXOPLASMA IgM** Code 91041
 LOT: **315** Code 91179
 DATE OF TEST: **15/11/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		<i>FOUND</i>	<i>EXPECTED</i>
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.521	
	CV%	12%	< 20%
2nd PLATE	OD 450 nm	1.529	
	CV%	9%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.763	
	CV%	12%	< 15%
2. BULK CONTROL date: 12/09/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.313	≥ 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: 15/11/2022			
A) Blank	OD 450 nm	0.051	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.109	< 0,6Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.269	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.243	> 1,5Cut Off
E) HOMOGENEITY OF CUT OFF			
No.		6	
OD 450 nm		0.320	
CV%		7%	≤ 15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **17-11-2022**

Signed: 
 Released: Q.C.Manager

Aggiornamento 07.2012