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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgM

Code	91041		
LOT. NO.	313	2023-07	2022-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93000	006330	MICROPLATE	662	2023-09	1
PF91540	006320	CONJUGATE	219	2023-07	1
PF93900/TXM	C5100	NEGATIVE CONTROL	743	2023-10	1
PF92042	005370	POSITIVE CONTROL	200	2023-10	1
PF91841	005120	CUT-OFF CONTROL	198	2023-10	1
PF91641	005130	ANTIGEN (3,0 mL)	204	2025-02	6
PF93611	009660	DILUENT 2	223	2023-08	1
PF93603	1035	WASHING BUFFER 10x	449-1	2023-11	1
PF93602	1032/RISK0	STOP SOLUTION	214-2	2024-02	1
PF93619	1034	SUBSTRATE-HS	361	2023-07	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.096	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.395	≥ 0.200
POSITIVE CONTROL	2.101	> 1,5 CUT-OFF
CV %	6%	≤ 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

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 IgM** Code 91041
 LOT: **313** Code 91179
 DATE OF TEST: **20/05/2022**

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE		FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.908	
	CV%	7%	< 20%
2nd PLATE	OD 450 nm	1.884	
	CV%	3%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.915	
	CV%	6%	< 15%
2. BULK CONTROL date: 16/05/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.405	≥ 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: 20/05/2022			
A) Blank	OD 450 nm	0.039	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.096	< 0,6Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.395	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.101	> 1,5Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	6	
	OD 450 nm	0.434	
	CV%	6%	≤ 15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **20.05.2022**

Signed:

Released: Q.C.Manager

Aggiornamento 07.2012