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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgM

Code 91041

LOT.NO 318



2025-01



2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006330	MICROPLATE	671	2025-03	1
PF91540	006320	CONJUGATE	223	2025-01	1
PF93900/TXM	C5100	NEGATIVE CONTROL	803	2025-04	1
PF92042	005370	POSITIVE CONTROL	204	2025-04	1
PF91841	005120	CUT-OFF CONTROL	203	2025-04	1
PF91641	005130	ANTIGEN (3,0 mL)	205	2026-01	6
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	462	2025-02	1
PF93602	1032/RISK0	STOP SOLUTION	218-5	2025-06	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.152	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.394	≥ 0.200
POSITIVE CONTROL	2.506	> 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: 27.10.2023

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 - 013-V



CODE 91041

CODE 91179

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT TOXOPLASMA IgM

LOT. 318

DATE OF TEST 25/10/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.129	
	CV%	13%	< 20%
2nd PLATE	OD 450 nm	1.254	
	CV%	5%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.380	
	CV%	10%	< 15%
2. BULK CONTROL date: 17/10/2023			
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: 25/10/2023			
A) Blank	OD 450 nm	0.063	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.152	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.394	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.506	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF			
	No.	5	
	OD 450 nm	0.458	
	CV%	13%	≤ 15%
F) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 25.10.2023

Signed:

Released: Q.C.Manager