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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgM

Code 91041

LOT.NO 320-B



2025-04



2024-02

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006330	MICROPLATE	674	2025-05	1
PF91540	006320	CONJUGATE	225	2025-04	1
PF93900/TXM	C5100	NEGATIVE CONTROL	815	2025-07	1
PF92042	005370	POSITIVE CONTROL	206	2025-07	1
PF91841	005120	CUT-OFF CONTROL	205	2025-07	1
PF91641	005130	ANTIGEN (3,0 mL)	205	2026-01	6
PF93611	009660	DILUENT 2	233	2025-07	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.149	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.444	≥ 0.200
POSITIVE CONTROL	2.628	> 1,5 CUT-OFF
CV %	15%	≤ 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: 22.05.2024

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 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. 320

DATE OF TEST 05/03/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

OD 450 nm 3.021

CV% 2%

< 20%

2nd PLATE

OD 450 nm 2.794

CV% 9%

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450 nm 3.057

CV% 5%

< 15%

2. BULK CONTROL date: 22/02/2024

A) Average OD of Cut Off Control

OD 450 nm 0.449

≥ 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: 05/03/2024

A) Blank

OD 450 nm 0.060

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.149

< 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.444

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 2.628

> 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No. 8

OD 450 nm 0.504

CV% 15%

≤ 15%

F) PRECISION OF FILLING PROCESS



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 05.03.2024

Signed:

Released: Q.C. Manager