

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgM

Code	91041		
LOT.NO	319	2025-02	2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006330	MICROPLATE	673	2025-05	1
PF91540	006320	CONJUGATE	224	2025-02	1
PF93900/TXM	C5100	NEGATIVE CONTROL	808	2025-05	1
PF92042	005370	POSITIVE CONTROL	205	2025-05	1
PF91841	005120	CUT-OFF CONTROL	204	2025-05	1
PF91641	005130	ANTIGEN (3,0 mL)	205	2026-01	6
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	466	2025-04	1
PF93602	1032/RISKO	STOP SOLUTION	218-5	2025-06	1
PF93619	1034	SUBSTRATE-HS	380-1	2025-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.068	< 0,6 CUT-OFF
CUT-OFF CONTROL	0.361	≥ 0.200
POSITIVE CONTROL	2.351	> 1,5 CUT-OFF
CV %	11%	≤ 15%

*Evaluatin 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: 23.11.23

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. 319
 DATE OF TEST 23/11/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.715 CV% 15%	< 20%
2nd PLATE	OD 450 nm 2.817 CV% 8%	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450 nm 2.707 CV% 7%	< 15%
2. BULK CONTROL date: 17/11/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.347	≥ 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: 23/11/2023		
A) Blank	OD 450 nm 0.046	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.068	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.361	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.351	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 5 OD 450 nm 0.407 CV% 11%	≤ 15%
F) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 23/11/2023

Signed:
Released: Q.C.Manager