

DIESSE DIAGNOSTICA SENESE SpA
53035 Monteriggioni (SI), Italy, Strada dei Laghi 39
Tel. +39 0577319554 FAX +39 0577319020



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

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL TOXOPLASMA IgG

Code 91040

LOT.NO 259

 2025-03

 2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93040	006290	MICROPLATE	226	2025-05	1
PF93506	006270	CONJUGATE	201	2025-03	1
PF93910	1036	IgG NEGATIVE CONTROL	179	2025-06	1
PF91840	005150	CALIBRATOR 1	188	2025-06	1
PF93842	005170	CALIBRATOR 2	188	2025-06	1
PF93843	005180	CALIBRATOR 3	188	2025-06	1
PF93844	005190	CALIBRATOR 4	188	2025-06	1
PF93845	005160	CALIBRATOR 5	188	2025-06	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
IgG NEG CONTROL 0	0.000	≤ 0,6 CUT-OFF
CALIBRATOR 1 8 (cut-off)	0.688	≥ 0.200
CALIBRATOR 2 20	1.355	
CALIBRATOR 3 50	2.226	
CALIBRATOR 4 100	2.584	
CALIBRATOR 5 200	3.553	≥ 1.500
CV %	4%	≤ 15%

*Evaluation of the method according to the package insert 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: 30.12.2024

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 - 012-V



CODE 91040

CODE 91178

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT TOXOPLASMA IgG

LOT. 259

DATE OF TEST 25/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

OD450 nm 1.779

CV% 4%

<20%

2nd PLATE

OD 450nm N/A

CV% N/A

<20%

B) UNIFORMITY WITHIN PLATE

OD 450nm 1.954

CV% 6%

<15%

2. BULK CONTROL date: 15/01/2024

A) Average OD of Cut Off Calibrator

OD 450 nm 0.743

≥ 0.350

B) Index of Negative and Positive Sera

accepted

According to specification

C) Sensitivity with working calibrators

accepted

According to specification

3. CONTROL OF COMPLETE KIT date: 25/01/2024

A) Substrate Blank

OD 450 nm 0.059

≤0.100

Calibrator 0 IU/ml

OD 450 nm 0.000

≤0,6 Cut Off

Calibrator 8 IU/ml (Cut Off)

OD 450 nm 0.688

≥0.200

Calibrator 20 IU/ml

OD 450 nm 1.355

Calibrator 50 IU/ml

OD 450 nm 2.226

Calibrator 100 IU/ml

OD 450 nm 2.584

Calibrator 200 IU/ml

OD 450 nm 3.553

≥1.500

B) HOMOGENEITY OF CUT OFF

No. 6

OD 450 nm 0.746

CV% 4%

≤15%

C) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 25.01.2024

Signed:

Released: Q.C.Manager