研究用試薬

Anti-Toxoplasma gondii ELISA (IgG)
Instructions for use

ORDER NO.	ANTIBODIES AGAINST	IG CLASS	SUBSTRATE	FORMAT
EI 2410-9601 G	Toxoplasma gondii	IgG	Ag-coated microplate wells	96 x 01 (96)

Indication: The enzyme immunoassay (ELISA) provides a semiquantitative or quantitative in vitro assay for human antibodies of the immunoglobulin class IgG against Toxoplasma gondii in serum or plasma to support the diagnosis of toxoplasmosis. The product is designed for use as IVD.

Principle of the test: The test kit contains microplate strips each with 8 break-off reagent wells coated with Toxoplasma gondii antigens. In the first reaction step, diluted patient samples are incubated in the wells. In the case of positive samples, specific IgG antibodies (also IgA and IgM) will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled anti-human IgG (enzyme conjugate) catalysing a colour reaction.

Contents of the test kit:

Component	Colour	Format	Symbol
1. Microplate wells coated with antigens 12 microplate strips each containing 8 individual break-off wells in a frame, ready for use	---	12 x 8	STRIPS
2. Calibrator 1 200 IU/ml (IgG, human), ready for use	dark red	1 x 2.0 ml	CAL 1
3. Calibrator 2 10 IU/ml (IgG, human), ready for use	red	1 x 2.0 ml	CAL 2
4. Calibrator 3 1 IU/ml (IgG, human), ready for use	light red	1 x 2.0 ml	CAL 3
5. Positive control (IgG, human), ready for use	blue	1 x 2.0 ml	POS CONTROL
6. Negative control (IgG, human), ready for use	green	1 x 2.0 ml	NEG CONTROL
7. Enzyme conjugate peroxidase-labelled anti-human IgG (rabbit), ready for use	green	1 x 12 ml	CONJUGATE
8. Sample buffer ready for use	light blue	1 x 100 ml	SAMPLE BUFFER
9. Wash buffer 10x concentrate	colourless	1 x 100 ml	WASH BUFFER 10x
10. Chromogen/substrate solution TMB/H_2O_2, ready for use	colourless	1 x 12 ml	SUBSTRATE
11. Stop solution 0.5 M sulphuric acid, ready for use	colourless	1 x 12 ml	STOP SOLUTION
12. Instructions for use	---	1 booklet	
13. Quality control certificate	---	1 protocol	

LOT	Lot description	CE 0197	Storage temperature
IVD	In vitro diagnostic medical device		Unopened usable until

Updates with respect to the previous version are marked in grey.

Preparation and stability of the reagents

Note: All reagents must be brought to room temperature (+18 °C to +25 °C) approx. 30 minutes before use. After first use, the reagents are stable until the indicated expiry date if stored at +2 °C to +8 °C and protected from contamination, unless stated otherwise below.

- **Coated wells:** Ready for use. Tear open the resealable protective wrapping of the microplate at the recesses above the grip seam. Do not open until the microplate has reached room temperature to prevent the individual strips from moistening. Immediately replace the remaining wells of a partly used microplate in the protective wrapping and tightly seal with the integrated grip seam. (Do not remove the desiccant bag).
  Once the protective wrapping has been opened for the first time, the wells coated with antigens can be stored in a dry place and at a temperature between +2 °C and +8 °C for 4 months.

- **Calibrators and controls:** Ready for use. The reagents must be mixed thoroughly before use.

- **Enzyme conjugate:** Ready for use. The enzyme conjugate must be mixed thoroughly before use.

- **Sample buffer:** Ready for use.

- **Wash buffer:** The wash buffer is a 10x concentrate. If crystallisation occurs in the concentrated buffer, warm it to +37 °C and mix well before diluting. The quantity required should be removed from the bottle using a clean pipette and diluted with deionised or distilled water (1 part reagent plus 9 parts distilled water).
  For example: For 1 microplate strip, 5 ml concentrate plus 45 ml water.
  The working-strength wash buffer is stable for 4 weeks month when stored at +2°C to +8°C and handled properly.

- **Chromogen/substrate solution:** Ready for use. Close the bottle immediately after use, as the contents are sensitive to light. The chromogen/substrate solution must be clear on use. Do not use the solution if it is blue coloured.

- **Stop solution:** Ready for use.

Storage and stability: The test kit has to be stored at a temperature between +2 °C to +8 °C. Do not freeze. Unopened, all test kit components are stable until the indicated expiry date.

Waste disposal: Patient samples, calibrators, controls and incubated microplate strips should be handled as infectious waste. All reagents must be disposed of in accordance with local disposal regulations.

Warning: The calibrators and controls of human origin have tested negative for HBsAg, anti-HCV, anti-HIV-1 and anti-HIV-2. Nonetheless, all materials should be treated as being a potential infection hazard and should be handled with care. Some of the reagents contain sodium azide in a non-declarable concentration. Avoid skin contact.

Preparation and stability of the patient samples

Samples: Human serum or EDTA, heparin or citrate plasma.

Stability: Patient samples to be investigated can generally be stored at +2 °C to +8 °C for up to 14 days. Diluted samples should be incubated within one working day.

Sample dilution: Patient samples are diluted **1:101** in sample buffer. For example: dilute 10 µl sample in 1.0 ml sample buffer and mix well by vortexing (sample pipettes are not suitable for mixing).

NOTE: The calibrators and controls are prediluted and ready for use, do not dilute them.

Incubation

For **semiquantative analysis** incubate **calibrator 2** along with the positive and negative controls and patient samples. For **quantitative analysis** incubate **calibrators 1, 2 and 3** along with the positive and negative controls and patient samples.

(Partly) manual test performance

Sample incubation: (1st step)
Transfer 100 µl of the calibrators, positive and negative controls or diluted patient samples into the individual microplate wells according to the pipetting protocol. Incubate for **30 minutes** at room temperature (+18 °C to +25 °C).

Washing:
Manual: Empty the wells and subsequently wash 3 times using 300 µl of working-strength wash buffer for each wash.
Automatic: Wash the reagent wells 3 times with 450 µl of working-strength wash buffer (program setting: e.g. TECAN Columbus Washer "Overflow Mode").

Leave the wash buffer in each well for 30 to 60 seconds per washing cycle, then empty the wells. After washing (manual and automated tests), thoroughly dispose of all liquid from the microplate by tapping it on absorbent paper with the openings facing downwards to remove all residual wash buffer.

Note: Residual liquid (> 10 µl) in the reagent wells after washing can interfere with the substrate and lead to false low extinction readings. Insufficient washing (e.g., less than 3 wash cycles, too small wash buffer volumes, or too short residence times) can lead to false high extinction readings.
Free positions on the microplate strip should be filled with blank wells of the same plate format as that of the parameter to be investigated.

Conjugate incubation: (2nd step)
Pipette 100 µl of enzyme conjugate (peroxidase-labelled anti-human IgG) into each of the microplate wells. Incubate for **30 minutes** at room temperature (+18 °C to +25 °C).

Washing:
Empty the wells. Wash as described above.

Substrate incubation: (3rd step)
Pipette 100 µl of chromogen/substrate solution into each of the microplate wells. Incubate for **15 minutes** at room temperature (+18 °C to +25 °C) (protect from direct sunlight).

Stopping:
Pipette 100 µl of stop solution into each of the microplate wells in the same order and at the same speed as the chromogen/substrate solution was introduced.

Measurement:
Photometric measurement of the colour intensity should be made at a **wavelength of 450 nm** and a reference wavelength between 620 nm and 650 nm **within 30 minutes of adding the stop solution**. Prior to measuring, slightly shake the microplate to ensure a homogeneous distribution of the solution.

Test performance using fully automated analysis devices

Sample dilution and test performance are carried out fully automatically using an analysis device. The incubation conditions programmed in the respective software authorised by EUROIMMUN may deviate slightly from the specifications given in the ELISA test instruction. However, these conditions were validated in respect of the combination of the EUROIMMUN Analyzer I, EUROIMMUN Analyzer I-2P and the DSX from Dynex and this EUROIMMUN ELISA. Validation documents are available on enquiry.
Automated test performance using other fully automated, open system analysis devices is possible. However, the combination should be validated by the user.

Pipetting protocol

	1	2	3	4	5	6	7	8	9	10	11	12
A	C 2	P 6	P 14	P 22			C 1	P 4	P 12	P 20		
B	pos.	P 7	P 15	P 23			C 2	P 5	P 13	P 21		
C	neg.	P 8	P 16	P 24			C 3	P 6	P 14	P 22		
D	P 1	P 9	P 17				pos.	P 7	P 15	P 23		
E	P 2	P 10	P 18				neg.	P 8	P 16	P 24		
F	P 3	P 11	P 19				P 1	P 9	P 17			
G	P 4	P 12	P 20				P 2	P 10	P 18			
H	P 5	P 13	P 21				P 3	P 11	P 19			

The pipetting protocol for microplate strips 1 to 4 is an example for the **semiquantitative analysis** of 24 patient sample (P 1 to P 24).
The pipetting protocol for microplate strips 7 to 10 is an example for the **quantitative analysis** of 24 patient sample (P 1 to P 24).

The calibrators (C 1 to C 3), the positive (pos.) and negative (neg.) controls, and the patient samples have each been incubated in one well. The reliability of the ELISA test can be improved by duplicate determinations for each sample.
The wells can be broken off individually from the strips. Therefore, the number of tests performed can be matched to the number of samples, minimising reagent wastage. Both positive and negative controls serve as internal controls for the reliability of the test procedure. They must be assayed with each test run.

Calculation of results

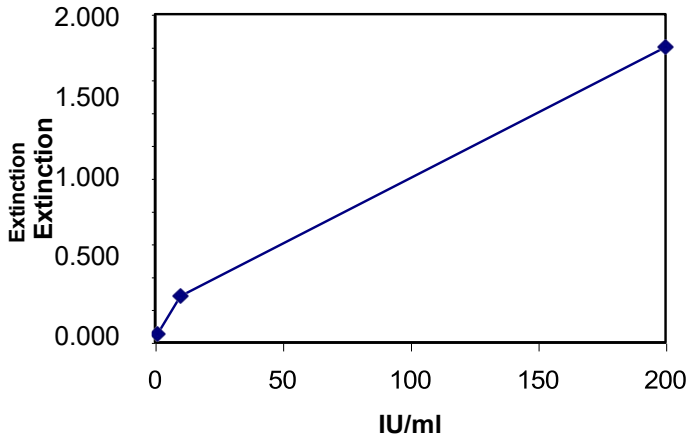
Semiquantitative: Results can be evaluated semiquantitatively by calculating a ratio of the extinction of the control or patient sample over the extinction of calibrator 2. Calculate the ratio according to the following formula:

$$\frac{\text{Extinction of the control or patient sample}}{\text{Extinction of calibrator 2}} = \text{Ratio}$$

EUROIMMUN recommends interpreting results as follows:

Ratio <0.8:	**negative**
Ratio ≥0.8 to <1.1:	**borderline**
Ratio ≥1.1:	**positive**

Quantitative: The standard curve from which the concentration of antibodies in the patient samples can be taken is obtained by point-to-point plotting of the extinction readings measured for the 3 calibrators against the corresponding units (linear/linear). Use “point-to-point” plotting for calculation of the standard curve by computer. The following plot is an example of a typical calibration curve. Please do not use this curve for the determination of antibody concentrations in patient samples.



If the extinction for a patient sample lies above the extinctions of calibrator 1 (corresponding to 200 IU/ml), the result should be reported as ">200 IU/ml". It is recommended that the sample be retested at a dilution of e.g. 1:400. The result in IU/ml read from the calibration curve for this sample must then be multiplied by factor 4.

The upper limit of the reference range of non-infected persons (**cut-off value**) recommended by EUROIMMUN is **10 international units (IU)/ml**.

EUROIMMUN recommends interpreting results as follows:

<8 IU/ml:	**negative**
≥8 to <11 IU/ml:	**borderline**
≥11 IU/ml:	**positive**

For duplicate determinations the mean of the two values should be taken. If the two values deviate substantially from one another, EUROIMMUN recommends retesting the samples.

A negative serological result does not exclude an infection. Particularly in the early phase of infection, antibodies may not yet be present or are only present in such small quantities that they are not detectable. In the case of a borderline result, a secure evaluation is not possible. If there is a clinical suspicion and a negative or borderline test result, we recommend clarification by means of other diagnostic methods and/or the serological investigation of a follow-up sample. A positive result indicates that there has been contact with the pathogen. In the determination of pathogen-specific IgM antibodies, polyclonal stimulation of the immune system or antibody persistence may affect the diagnostic relevance of positive findings. Significantly higher specific IgG antibody levels (increase by more than factor 2) and/or seroconversion in a follow-up sample taken after at least 7 to 10 days can indicate an acute infection. Sample and follow-up sample should be incubated in parallel in adjacent wells of the ELISA microplate within the same test run. For diagnosis, the clinical picture of the patient always needs to be taken into account along with the serological findings.

Test characteristics

Calibration: The calibration is performed in international units (IU) using the 3rd international standard preparation of the World Health Organization (WHO) (The 3rd International Standard for Anti-Toxoplasma Serum, Human. Code TOXM. National Institute for Biological Standards and Control, Hertfordshire, England).

For every group of tests performed, the extinction readings of the calibrators and the international units and/or ratios determined for the positive and negative controls must lie within the limits stated for the relevant test kit lot. A quality control certificate containing these reference values is included. If the values specified for the controls are not achieved, the test results may be inaccurate and the test should

be repeated.

The binding activity of the antibodies and the activity of the enzyme used are temperature-dependent. It is therefore recommended using a thermostat in all three incubation steps. The higher the room temperature (+18 °C to +25 °C) during the incubation steps, the greater will be the extinction. Corresponding variations apply also to the incubation times. However, the calibrators are subject to the same influences, with the result that such variations will be largely compensated in the calculation of the result.

Antigen: The reagent tubes used in this ELISA were coated with ultrasound-treated lysates from *Toxoplasma gondii* tachyzoites.

Linearity: The linearity of the Anti-Toxoplasma gondii ELISA (IgG) was determined by assaying 4 serial dilutions of different patient samples. The coefficient of determination R^2 for all sera was > 0.95. The Anti-Toxoplasma gondii ELISA (IgG) is linear at least in the tested concentration range (1 IU/ml to 200 IU/ml).

Detection limit: The lower detection limit is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest detectable antibody concentration. The lower detection limit of the Anti-Toxoplasma gondii ELISA (IgG) is 0.3 IU/ml.

Cross reactivity: The quality of the antigen used ensures a high specificity of the ELISA. Sera from patients with infections caused by various agents were investigated with the Anti-Toxoplasma gondii ELISA (IgG).

Antibodies against	n	Positive in Anti-Toxoplasma gondii ELISA (IgG)
Adenovirus	12	0%
Chlamydia pneumoniae	8	0%
CMV	12	0%
EBV-CA	12	0%
Helicobacter pylori	12	0%
HSV-1	12	0%
Influenza virus A	12	0%
Influenza virus B	12	0%
Measles virus	12	0%
Mumps virus	12	0%
Mycoplasma pneumoniae	12	0%
Parainfluenza virus Pool	12	0%
RSV	12	0%
Rubella virus	12	0%
VZV	12	0%

Interference: Haemolytic, lipaemic and icteric samples showed no influence on the result up to concentrations of 10 mg/ml haemoglobin, 20 mg/ml triglycerides and 0.4 mg/ml bilirubin in this ELISA.

Reproducibility: The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation (CV) using 3 samples. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on 4 determinations performed in 6 different test runs.

Intra-assay variation, n = 20		
Sample	**Mean value (IU/ml)**	**CV (%)**
1	7	2.9
2	83	5.3
3	130	4.7

Inter-assay variation, n = 4 x 6		
Sample	**Mean value (IU/ml)**	**CV (%)**
1	7	4.4
2	88	4.2
3	126	2.9

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Sensitivity and specificity:
Study I: 230 pre-characterised patient samples (origin: Europe; reference method: commercially available FDA registered ELISA of another manufacturer) were investigated with the EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG). The sensitivity amounted to 100%, with a specificity of 100%. Borderline results were not included in the calculation.

n = 230		ELISA of another manufacturer (FDA registered)		
		positive	borderline	negative
EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG)	positive	180	1	0
	borderline	2	1	0
	negative	0	1	45

Study II: 92 pre-characterised patient samples (origin: Europe; reference method: commercially available ELISA of another manufacturer) were investigated with the EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG). The sensitivity amounted to 100%, with a specificity of 100%. Borderline results were not included in the calculation.

n = 92		ELISA of another manufacturer		
		positive	borderline	negative
EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG)	positive	56	1	0
	borderline	0	0	1
	negative	0	2	32

Study III: 385 clinically pre-characterised patient samples (INSTAND, NEQAS Labquality, MQ and RfB) were investigated with the EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG). The sensitivity amounted to 99.6%, with a specificity of 100%. Borderline results were not included in the calculation.

n = 385		NEQAS/INSTAND/Labquality/MQ/RfB		
		positive	borderline	negative
EUROIMMUN Anti-Toxoplasma gondii ELISA (IgG)	positive	257	0	0
	borderline	6	0	0
	negative	1	0	121

Reference range: Levels of anti-Toxoplasma gondii antibodies were investigated in a panel of healthy blood donors (n = 500, origin: Germany) using the EUROIMMUN ELISA. With a cut-off value of 10 IU/ml, 38.6% of the blood donors were anti-Toxoplasma gondii positive (IgG), in agreement with the known level of immunity in adults from this region.

Limitations of the procedure

The test is not intended to be used for the determination of suitability for transfusion, transplantation or cell administration.

Clinical significance

The sporozoon Toxoplasma gondii is the causative agent of the worldwide distributed zoonosis toxoplasmosis. The main host animal is the cat. The parasites live in the intestinal cells of the host and cause oocysts to develop (sexual development cycle). During the asexual cycle, the Toxoplasma parasites develop in the brain, muscles, liver, spleen and in other organs of warm-blooded animals, where they become encapsulated. Humans are generally infected perorally by ingestion of oocysts with viable trophozoites, which are contained in the faeces of infected cats or in meat products (raw flesh) from infected animals. Toxoplasma gondii can also be transmitted diaplacentally when a pregnant woman is first infected. In Germany, the risk of infection is particularly high, since 65% to 75% of women of childbearing age are negative for IgG antibodies against Toxoplasma.

Post-natally acquired toxoplasmosis proceeds inapparently in 90% of cases. Cysts containing trophozoites form in the tissues and can persist for years. Acute or previous infections can therefore only be identified serologically. The symptoms of the manifest disease include fever, lymphadenopathy, encephalitis, chorioretinitis, myositis, myocarditis, pneumonia, hepatosplenomegaly and exanthema, depending on the affected organs. In immunocompromised patients (recipients of transplants, tumour patients, HIV-infected patients), a primary infection with Toxoplasma or the reactivation of toxoplasmosis can lead to a life-threatening illness.

After an intrauterine infection with Toxoplasma gondii in the first trimester, placenta and embryo are severely affected, resulting in rejection of the embryo. An infection in the second or third trimester results in foetal symptoms which vary in intensity depending on the time point of infection, the dose of the infection and the immune status of mother and foetus. Among the most important symptoms are the following: hepatosplenomegaly, pneumonia, myocarditis, purpura, hydrocephalus and intracranial anomalies (in particular intracerebral calcification), chorioretinitis and optic nerve oedema with concurrent distant active lesions. Connatally infected children mostly show severe damage, as they are treated too late.

If the Toxoplasma immune status is not known at the start of a pregnancy, the obstetrician should advise the patient on potential infection sources, risks of a potential Toxoplasma infection for the child, preventative measures and the possibility of serological diagnostics. Infections that can present a prenatal risk to the unborn child are combined under the term of TORCH complex: T = toxoplasmosis, O = "other infectious microorganisms“, R = rubella, C = cytomegalovirus infection, H = Herpes simplex. Within TORCH infections in pregnant women the seroprevalence of IgM antibodies against Toxoplasma gondii varies. It is between 15% and 75%, depending on the country.

PCR from blood samples for the diagnosis of acute infection is often not useful in immunocompetent persons because a negative result does not reliably exclude very recent parasitaemia. Positive PCR results from blood samples in the acute phase of infection are mostly incidental findings. Serology is therefore the method of choice for the diagnosis of acute infection.

The standard methods for the serological detection of Toxoplasma-specific IgG and IgM antibodies are IIFT and ELISA. Due to the fact that the diagnostic sensitivity varies and the specificity of serological IgM analysis is generally lower than that of IgG analysis, IgA antibodies and avidity should be investigated in ambiguous cases. The detection of low-avidity antibodies against Toxoplasma gondii in the serum allows the diagnosis of acute Toxoplasma infection.

Interpretation of results:

IgG	**IgM**	**IgG avidity**	**Probable result**
positive	negative	-	inactive latent infection
positive	positive	high	abating or latent (inactive) infection
positive	positive	low	further serological testing/monitoring required

The use of the Anti-Toxoplasma gondii Screen ELISA as a combined test is recommended for a strategic diagnostic approach in the serological diagnosis of Toxoplasma gondii infections. The sensitivity is 100%. Antibodies of classes IgG and IgM (sometimes also IgA) can be investigated with one procedure and no loss in specificity. The Anti-Toxoplasma gondii Screen ELISA is particularly recommended in countries with a low prevalence, such as Germany, to save costs. In regions with a high prevalence and therefore high IgG detection rates, the monospecific standard tests should be carried out. This approach is also recommended by the Robert Koch Institute in Berlin, Germany.

Furthermore, in addition to serum diagnostics, CSF analysis is very important to detect rare cases of specific antibody synthesis in the central nervous system. The CSF/serum quotient allows differentiation between a blood-derived and a pathological, intrathecal antibody fraction in the CSF, taking into account individual changes in the blood/CSF barrier function. The frequently observed discrepancy between antibody concentrations in serum and CSF is due to local synthesis of antibodies (IgG) against Toxoplasma gondii in the central nervous system, which can persist for several years.

Literature

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Liability

The test kit, including original accessories, must only be used in accordance with the intended use. EUROIMMUN accepts no liability for any other use (e.g. non-compliance with the instructions for use and improper use) or for resulting damages.

Technical Support

In case of technical problems you can obtain assistance via the EUROIMMUN website (https://www.euroimmun.de/en/contact/).

Additional information

Regulatory information for customers in the European Union: Please observe the obligation to report any serious incidents occurring in connection with this product to the competent authorities and to EUROIMMUN.

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