

# Toxo IgG

IgG antibodies to *Toxoplasma gondii***cobas**<sup>®</sup>

REF		SYSTEM
04618815 190	100	Elecsys 2010 MODULAR ANALYTICS E170 <b>cobas e 411</b> <b>cobas e 601</b> <b>cobas e 602</b>

## English

### Please note

The measured anti-Toxo IgG value of a patient's sample can vary depending on the testing procedure used. The laboratory finding must therefore always contain a statement on the Toxo IgG assay method used. Anti-Toxo IgG values determined on patient samples by different testing procedures cannot be directly compared with one another and could be the cause of erroneous medical interpretations.

Therefore, the results reported by the laboratory to the physician should include: "The following results were obtained with the Elecsys Toxo IgG assay. Results from assays of other manufacturers cannot be used interchangeably."

### Intended use

Immunoassay for the in vitro quantitative determination of IgG antibodies to *Toxoplasma gondii* in human serum and plasma.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

### Summary

Toxoplasmosis is a common infection caused by the protozoan parasite *Toxoplasma gondii*.

The infection is mainly acquired by ingestion of food or water that is contaminated by mature oocysts shed by cats or by undercooked meat containing tissue cysts.<sup>1</sup>

Primary, acute infection which is mostly mild or even asymptomatic in healthy individuals, is followed by a latent infection which usually persists for life. However, reactivation of a latent *Toxoplasma* infection as a result of immunosuppression (e.g. in organ transplant recipients, AIDS patients) is frequently associated with meningoencephalitis.<sup>2,3</sup>

Primary maternal *Toxoplasma* infection occurring during pregnancy may lead to severe damage of the fetus as the parasite can be transmitted across the placenta. The majority of infants with congenital infection do not present clinical symptoms at birth but may develop severe sequelae later in life like mental and psychomotor retardation, chorioretinitis and hearing loss.<sup>4</sup> The fetal infection rate increases with gestational age. However, the risk of severe clinical manifestations is higher in case of early maternal infection.<sup>4,5,6</sup>

Early drug therapy in acute infection during pregnancy can prevent congenital damage or ameliorate the severity of clinical manifestations.<sup>4,5,6</sup>

The diagnosis of *Toxoplasma* infection is most commonly made by the detection of anti-*Toxoplasma*-specific IgG and IgM antibodies.

The determination of IgG antibodies to *Toxoplasma gondii* is used to assess the serological status to *T. gondii* and is indicative of an acute or latent infection.

The detection of IgM antibodies to *T. gondii* could indicate an acute, recent or reactivated *Toxoplasma* infection.

The diagnosis of the acute acquired infection during pregnancy is established by a seroconversion or a significant rise in antibody titers (IgG and/or IgM) in serial samples.<sup>4,6</sup>

### Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 10 µL of sample, a biotinylated recombinant *T. gondii*-specific antigen, and a *T. gondii*-specific recombinant antigen labeled with a ruthenium complex<sup>a)</sup> form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)<sub>3</sub><sup>2+</sup>)

### Reagents - working solutions

The reagent rackpack (M, R1, R2) is labeled as TOXIGG.

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL:  
Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 *Toxoplasma*-Ag-biotin (gray cap), 1 bottle, 9 mL:  
Biotinylated *T. gondii*-specific antigen (recombinant, *E. coli*), > 400 µg/L, TRIS buffer 50 mmol/L, pH 7.5; preservative.
- R2 *Toxoplasma*-Ag-Ru(bpy)<sub>3</sub><sup>2+</sup> (black cap), 1 bottle, 9 mL:  
*T. gondii*-specific antigen (recombinant, *E. coli*) labeled with ruthenium complex > 400 µg/L; TRIS buffer 50 mmol/L, pH 7.5; preservative.

TOXIGG Cal1 Negative calibrator 1 (white cap), 2 bottles of 1.0 mL each:  
Human serum, non-reactive for anti-*Toxoplasma* IgG; buffer; preservative.

TOXIGG Cal2 Positive calibrator 2 (black cap), 2 bottles of 1.0 mL each:  
Human serum, reactive for anti-*Toxoplasma* IgG, approximately 100 IU/mL; buffer; preservative.

### Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

All human material should be considered potentially infectious.

Both calibrators (TOXIGG Cal1, TOXIGG Cal2) have been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV.

The serum containing anti-*Toxoplasma* IgG (TOXIGG Cal2) was sterile filtrated.

The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.<sup>7,8</sup>

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

### Reagent handling

The reagents in the kit are ready for use and are supplied in bottles compatible with the system.

Elecsys 2010 and **cobas e 411** analyzers: The calibrators should only be left on the analyzers during calibration at 20-25 °C. After use, close the bottles as soon as possible and store upright at 2-8 °C.

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Due to possible evaporation effects, not more than 5 calibration procedures per calibrator bottle set should be performed.

MODULAR ANALYTICS E170, **cobas e 601** and **cobas e 602** analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the ready-for-use calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °C for later use.

Perform **only one** calibration procedure per aliquot.

All information required for correct operation is read in from the respective reagent barcodes.

*Please note:* Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for **cobas 8000** systems only. If using a **cobas 8000** system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument as usual.

## Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the Elecsys reagent kit **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the reagent rackpack	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	12 weeks
on the analyzers	2 weeks or 12 weeks if stored alternately in the refrigerator and on the analyzers (up to 84 hours)

Stability of the calibrators	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	8 weeks
on Elecsys 2010 and <b>cobas e 411</b> at 20-25 °C	up to 5 hours
on MODULAR ANALYTICS E170, <b>cobas e 601</b> and <b>cobas e 602</b> at 20-25 °C	use only once

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

## Specimen collection and preparation

Only the specimens listed below were tested in a sufficient number and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin, K<sub>2</sub>-EDTA, K<sub>3</sub>-EDTA and Na-citrate plasma.

**Criterion:** Mean recovery of positive samples within 80-120 % of serum value.

Stable for 3 weeks at 2-8 °C, 3 days at 25 °C, 3 months at -20 °C. The samples may be frozen 6 times.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Specimens should not be subsequently altered with additives (biocides, anti-oxidants or substances that could possibly change the pH of the sample) in order to avoid erroneous findings. Pooled samples and other artificial material may have different effects on different assays and thus may lead to discrepant findings.

Centrifuge samples containing precipitates and frozen samples before performing the assay. Lyophilized samples, heat-inactivated samples and samples and controls stabilized with azide (up to 0.1 %) can be used.

Ensure the samples, calibrators and controls are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/measured within 2 hours.

## Materials provided

See "Reagents – working solutions" section for reagents.

## Materials required (but not provided)

- [REF] 04618823190, PreciControl Toxo IgG, 8 x 1 mL each of PreciControl Toxo IgG 1 and 2
  - [REF] 11732277122, Diluent Universal, 2 x 16 mL sample diluent or [REF] 03183971122, Diluent Universal, 2 x 36 mL sample diluent
  - [REF] 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
  - General laboratory equipment
  - Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** analyzer
- Accessories for Elecsys 2010 and **cobas e 411** analyzers:
- [REF] 11662988122, ProCell, 6 x 380 mL system buffer
  - [REF] 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
  - [REF] 11930346122, Elecsys SysWash, 1 x 500 mL washwater additive
  - [REF] 11933159001, Adapter for SysClean
  - [REF] 11706802001, Elecsys 2010 AssayCup, 60 x 60 reaction vessels
  - [REF] 11706799001, Elecsys 2010 AssayTip, 30 x 120 pipette tips

Accessories for MODULAR ANALYTICS E170, **cobas e 601** and **cobas e 602** analyzers:

- [REF] 04880340190, ProCell M, 2 x 2 L system buffer
- [REF] 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- [REF] 03023141001, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
- [REF] 03005712190, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
- [REF] 12102137001, AssayTip/AssayCup Combimagazine M, 48 magazines x 84 reaction vessels or pipette tips, waste bags
- [REF] 03023150001, WasteLiner, waste bags
- [REF] 03027651001, SysClean Adapter M

Accessories for all analyzers:

- [REF] 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

## Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically prior to use. Read in the test-specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.

Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Place the calibrators in the sample zone.

All the information necessary for calibrating the assay is automatically read into the analyzer.

After calibration has been performed, store the calibrators at 2-8 °C or discard (MODULAR ANALYTICS E170, **cobas e 601** and **cobas e 602** analyzers).

## Calibration

**Traceability:** This method has been standardized against the 3rd International Standard for anti-Toxoplasma serum (TOXM) from NIBSC, UK.

Every Elecsys Toxo IgG reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The

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predefined master curve is adapted to the analyzer using TOXIGG Cal1 and TOXIGG Cal2.

**Calibration frequency:** Calibration must be performed once per reagent lot using TOXIGG Cal1, TOXIGG Cal2 and fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

Renewed calibration is recommended as follows:

- after 1 month (28 days) when using the same reagent lot
- after 7 days (when using the same reagent kit on the analyzer)
- as required: e.g. quality control findings with PreciControl Toxo IgG outside the defined limits
- more frequently when this is required by pertinent regulations

### Quality control

For quality control, use PreciControl Toxo IgG.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

### Calculation

The analyzer automatically calculates the analyte concentration of each sample in IU/mL.

#### Interpretation of the results

Results obtained with the Elecsys Toxo IgG assay should be interpreted as follows taking into consideration the respective algorithm which is used for the screening of *Toxoplasma* in pregnant women according to national or regional guidelines or recommendations.

#### 1. Toxo IgG testing is used as first line screening assay

Non-reactive: < 1 IU/mL

Indeterminate: ≥ 1- < 3 IU/mL

Reactive: ≥ 3 IU/mL

Samples with concentrations < 1 IU/mL are considered non-reactive in the Elecsys Toxo IgG assay.

Samples with concentrations ≥ 3 IU/mL are considered positive for IgG antibodies to *T. gondii* and indicate either acute or latent infection.

For all samples with concentrations ≥ 3 IU/mL a Toxo IgM test should be performed to exclude early *Toxoplasma* infection.

Samples with concentrations ≥ 3- < 30 IU/mL and a negative IgM test result: A second sample should be collected e.g. within 3 weeks to exclude early *Toxoplasma* infection shown by a significant increase of the Toxo IgG antibody titer.

Samples between 1 IU/mL and < 3 IU/mL are considered indeterminate. The sample should be retested. In case the result is still indeterminate, a second sample should be collected e.g. within 3 weeks.

#### 2. Toxo IgG and Toxo IgM testing is done in parallel in all samples

Non-reactive: < 1 IU/mL

Indeterminate: ≥ 1- < 30 IU/mL

Reactive: ≥ 30 IU/mL

Samples with concentrations < 1 IU/mL are considered non-reactive in the Elecsys Toxo IgG assay.

Samples with concentrations between 1 IU/mL and < 30 IU/mL are considered indeterminate. The sample should be retested. In case the result is still indeterminate a second sample should be collected e.g. within 3 weeks. A persistent detection of concentrations between 1 IU/mL and < 30 IU/mL should be considered as indeterminate and a serological follow-up should be done.

Samples with concentrations ≥ 30 IU/mL are considered positive for IgG antibodies to *T. gondii* and indicate either acute or latent infection.

The diagnosis of acute *Toxoplasma* infection is supported by a significant increase of the Toxo IgG antibody titer (also within the range of 1 IU/mL and

< 30 IU/mL) from a first to a second sample taken e.g. within 3 weeks and in addition by *Toxoplasma*-specific IgM results.

#### Note:

*An indeterminate or low positive result may already indicate an early acute Toxoplasma infection (also in the absence of Toxo IgM antibodies).*

The anti-*Toxoplasma* IgG results in a given specimen, as determined by assays from different manufacturers, can vary due to differences in assay and reagent methods. Therefore, the results reported by the laboratory to the physician should include: "The following results were obtained with the Elecsys Toxo IgG assay. Results from assays of other manufacturers cannot be used interchangeably."

### Limitations - interference

A negative test result does not completely rule out the possibility of an infection with *T. gondii*. Individuals may not exhibit any detectable IgG antibodies at the early stage of acute infection.

The detection of *Toxoplasma*-specific IgG antibodies in a single sample indicates a previous exposure to *T. gondii* but is not sufficient to distinguish between an acute or latent infection (irrespective of the level of the IgG antibody titer).

For monitoring of the *Toxoplasma*-specific IgG antibody titer it is recommended to test serial samples by parallel measurements.

If a treatment is prescribed early enough, antibody production may not increase. IgG and IgM levels may remain low and can coexist for years.

Elecsys Toxo IgG results should be used in conjunction with the patient's medical history, clinical symptoms and other laboratory tests, e.g. *Toxoplasma*-specific IgM results, *Toxoplasma* avidity results.

The results in HIV patients, in patients undergoing immunosuppressive therapy, or in patients with other disorders leading to immune suppression, should be interpreted with caution.

Specimens from neonates, cord blood, pretransplant patients or body fluids other than serum and plasma, such as urine, saliva or amniotic fluid have not been tested.

The assay is unaffected by icterus (bilirubin < 684 µmol/L or < 40 mg/dL), hemolysis (Hb < 1.24 mmol/L or < 2 g/dL), lipemia (Intralipid < 2000 mg/dL) and biotin (< 246 nmol/L or < 60 ng/mL).

Criterion: Mean recovery of positive samples within ± 20 % of serum value.

Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

No interference was observed from rheumatoid factors up to a concentration of 6210 IU/mL.

In vitro tests were performed on 18 commonly used pharmaceuticals and in addition on spiramycine, sulfadiazine, folic acid and pyrimethamine. No interference with the assay was found.

In rare cases, interference due to extremely high titers of antibodies to immunological components, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

### Limits and ranges

#### Measuring range

0.13-650 IU/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 0.13 IU/mL. Values above the measuring range are reported as > 650 IU/mL (or up to 13000 IU/mL for 20-fold diluted samples).

#### Lower limits of measurement

*Lower detection limit of the test*

Lower detection limit: 0.13 IU/mL

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 21).

#### Dilution

Samples with anti-Toxo IgG concentrations above the measuring range can be diluted with Diluent Universal. The recommended dilution is 1:20 (either automatically by the MODULAR ANALYTICS E170, Elecsys 2010 and

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cobas e analyzers or manually). The concentration of the diluted sample must be  $\geq 3$  IU/mL.

After manual dilution, multiply the result by the dilution factor.

After dilution by the analyzers, the MODULAR ANALYTICS E170, Elecsys 2010 and cobas e software automatically takes the dilution into account when calculating the sample concentration.

Manual dilution can also be made with human serum negative for Toxo IgG.

**Note:** Antibodies to *Toxoplasma gondii* are heterogeneous. This may lead to non-linear dilution behavior.

A similar dilution behavior within the measuring range was shown when serial samples from the same individual were diluted. Paired serial samples of  $n = 12$  were examined. In a panel consisting of 30 samples with a concentration within the measuring range no higher Toxo IgG values were found upon dilution (if the dilution factor has not been taken into account).

## Expected values

The prevalence of IgG antibodies to *T. gondii* varies considerably depending upon geographical location and age of the population studied.

The Elecsys Toxo IgG assay was used to test 996 samples from clinical routine in France (site 1) and 1001 samples from clinical routine in Germany (site 2). Out of these 231 (23.2 %, France) and 376 (37.6 %, Germany) were found positive or indeterminate with the Elecsys Toxo IgG assay.

A distribution of these values is given in the following table:

IU/mL	Site 1, France, n = 996		Site 2, Germany, n = 1001	
	N	% of total	N	% of total
< 1	765	76.8	625	62.5
1-< 3	1	0.1	9	0.9
3-<10	1	0.1	3	0.3
10-< 100	26	2.61	46	4.6
100-< 300	79	7.93	158	15.8
300-< 650	83	8.33	99	9.9
> 650	41	4.12	61	6.1

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

## Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

### Precision

Precision was determined using Elecsys reagents, human sera and controls (repeatability  $n = 21$ , intermediate precision  $n = 10$ ); intermediate precision on MODULAR ANALYTICS E170 analyzer was determined in a modified protocol (EP5-A) of the CLSI (Clinical and Laboratory Standards Institute): 6 times daily for 10 days ( $n = 60$ ). The following results were obtained:

Elecsys 2010 and cobas e 411 analyzers						
Sample	Repeatability			Intermediate precision		
	Mean IU/mL	SD IU/mL	CV %	Mean IU/mL	SD IU/mL	CV %
HS <sup>b)</sup> , negative	0	-	-	0.046	-	-
HS, positive	22.2	0.414	1.9	21.2	0.854	4.0
HS, positive	316	5.03	1.6	296	10.7	3.6
PC <sup>c)</sup> Toxo IgG 1	0.767	0.019	2.5	0.821	0.022	2.7
PC Toxo IgG 2	48.6	0.774	1.6	50.5	1.53	3.0

b) HS = human serum

c) PC = PreciControl

MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers						
Sample	Repeatability			Intermediate precision		
	Mean IU/mL	SD IU/mL	CV %	Mean IU/mL	SD IU/mL	CV %
HS, negative	0.019	-	-	0.013	-	-
HS, positive	21.7	0.335	1.5	22.8	0.969	4.2
HS, positive	299	3.74	1.3	327	17.4	5.3
PC Toxo IgG 1	0.879	0.014	1.6	0.836	0.047	5.7
PC Toxo IgG 2	50.2	1.06	2.1	49.9	1.49	3.0

## Analytical specificity

232 potentially cross reacting samples were tested with the Elecsys Toxo IgG assay and a comparison Toxo IgG assay comprising specimens:

- containing antibodies against HBV, HCV, HIV\*\*, CMV, EBV, HSV, VZV\*\*, Parvo B19, Rubella, Treponema pallidum, Malaria\*, Amebiasis, Chlamydia and Gonorrhoea
- containing autoantibodies (AMA, ANA)
- after vaccination against HBV and Influenza

An overall agreement of 97.8 % (221/226) was found in these specimens with the Elecsys Toxo IgG assay and the comparison test. 127 samples were found concordantly negative and 94 samples were found positive. 6 samples were found indeterminate either with the Elecsys Toxo IgG assay or the comparison test.

\* Malaria: 3 samples which were found discordant positive with the Elecsys Toxo IgG assay, revealed also a positive result by a direct agglutination assay.

\*\*VZV: 1 discordant positive sample; HIV: 1 discordant negative sample with the Elecsys Toxo IgG assay

## Method comparison

A total of 2225 fresh and frozen samples analyzed by commercially available Toxoplasma IgG assays were tested with the Elecsys Toxo IgG assay at 4 sites. All specimens with discordant results were re-tested.

Resolution of repeatedly discordant samples was done using a second commercial Toxoplasma IgG assay at site 2 and by using a direct agglutination assay or a Toxo IgG-specific immunofluorescence test at site 3, 4 and 5.

23 specimens with indeterminate results in one of the assays were excluded from the final calculation of relative sensitivity and specificity.

Relative sensitivity and specificity after resolution

Study	N	Relative sensitivity (%)	Lower confidence limit (%)	Relative specificity (%)	Lower confidence limit (%)
2	992	100 (317/317)	99.1	99.8 (625/626)	99.2
3	439	99.5 (191/192)	97.5	98.8 (239/242)	96.8
4	380	100 (220/220)	98.7	100 (159/159)	98.1
5	391	100 (188/188)	98.4	99.0 (200/202)	98.5

Site 2: Of 50 samples which were initially discordant positive with the Elecsys Toxo IgG assay, 49 samples were also found positive in a second commercial Toxo IgG test.

Site 3: Of 8 samples which were initially discordant positive with the Elecsys Toxo IgG assay, 5 samples were found positive by a direct agglutination test.

Site 4: 1 sample which was initially discordant positive with the Elecsys Toxo IgG assay was found positive by a direct agglutination test.

Site 5: Of 3 samples which were initially discordant positive with the Elecsys Toxo IgG assay, 1 sample was found positive by an immunofluorescence IgG test.

## Seroconversion panels

In two studies seroconversion samples obtained during pregnancy screening were tested with the Elecsys Toxo IgG assay in comparison to two different commercially available Toxo IgG assays.

In 24 seroconversion panels comprising 85 samples at the first site, the Elecsys Toxo IgG assay detected 63 samples as positive or indeterminate.

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55 samples were found positive or indeterminate by the comparison test. In 29 seroconversion panels including 92 samples at the second site, 61 samples were detected positive or indeterminate by the Elecsys Toxo IgG assay while 45 samples were found positive or indeterminate by the comparison test.

### References

- 1 Montoya JG, Liesenfeld O. Toxoplasmosis. *Lancet* 2004;363:1965-1976.
- 2 Luft BJ, Remington JS. Toxoplasmic encephalitis in AIDS. *Clin Infect Dis* 1992;15:211-222.
- 3 Khalifa KES, Roth A, Roth B, et al. Value of PCR for Evaluating Occurrence of Parasitemia in Immunocompromised Patients with Cerebral and Extracerebral Toxoplasmosis. *J Clin Microbiol* 1994;32:2813-2819.
- 4 Remington JS, McLeod R, Desmonts G. Toxoplasmosis. *Infectious Diseases of the Fetus and Newborn Infant*, 5th ed. W.B. Saunders: Philadelphia, 2001;205-346.
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- 6 Wong SY, Remington JS. Toxoplasmosis in pregnancy. *Clin Infect Dis* 1994;18:853-862.
- 7 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 8 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume after reconstitution or mixing
	Global Trade Item Number

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