

REF			SYSTEM
07028008190	07028008500	300	cobas e 402 cobas e 801

English

System information

Short name	ACN (application code number)
TOXOIGG	10047

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 **cobas e** immunoassay analyzers.

Summary

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

The infection is mainly acquired by ingestion of food or water contaminated by mature oocysts shed by cats or by undercooked meat containing tissue cysts.^{1,2,3,4} Infection can also be transmitted congenitally if a woman is newly infected during or just prior to pregnancy, and via organ transplant or blood transfusion from an infected donor.⁴

Primary, acute infection in healthy individuals is mostly mild or even asymptomatic and is followed by life-long latency.^{3,4} Reactivation of a latent *Toxoplasma* infection can occur as a result of immunosuppression (e.g. in organ transplant recipients, patients with cancer or HIV) and can be associated with high morbidity and mortality.^{3,4} Reactivated disease in immunocompromised hosts frequently presents with brain lesions, especially in patients with advanced HIV-related immunosuppression.^{3,4,5}

Primary maternal *Toxoplasma* infection occurring during pregnancy may have significant implications for the fetus as the parasite can be transmitted across the placenta.^{3,6} The majority of infants with congenital infection do not present clinical symptoms at birth but may develop severe sequelae later in life such as chorioretinitis, intellectual and psychomotor disabilities, visual and hearing impairment and hearing loss.^{3,6,7,8} The fetal infection rate increases with gestational age, but the risk of severe clinical manifestations is higher in the case of early maternal infection.^{3,6,7,8}

Early drug therapy in acute infection during pregnancy can prevent congenital damage or ameliorate the severity of clinical manifestations.^{6,7}

The diagnosis of *Toxoplasma* infection is most commonly made by the detection of anti-*Toxoplasma*-specific IgG and IgM antibodies.^{3,4,9}

The determination of Toxo IgG antibodies is used to assess the serological status of *T. gondii* infection and their presence is indicative of a latent or acute infection.^{4,9}

Detection of Toxo IgM antibodies is presumptive of an acute or recent *Toxoplasma* infection.^{3,4,9}

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.^{8,9}

Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 6 µL of sample, a biotinylated recombinant *T. gondii*-specific antigen, and a *T. gondii*-specific recombinant antigen labeled with a ruthenium complex^{a)} 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 II 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 **cobas** link.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex (Ru(bpy)₃²⁺)

Reagents - working solutions

The **cobas e** pack (M, R1, R2) is labeled as TOXOIGG.

M Streptavidin-coated microparticles, 1 bottle, 14.1 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 *Toxoplasma*-Ag-biotin, 1 bottle, 19.7 mL:
Biotinylated *T. gondii*-specific antigen (recombinant, *E. coli*) > 400 µg/L, TRIS^{b)} buffer 50 mmol/L, pH 7.5; preservative.

R2 *Toxoplasma*-Ag-Ru(bpy)₃²⁺, 1 bottle, 19.7 mL:
T. gondii-specific antigen (recombinant, *E. coli*) labeled with ruthenium complex > 400 µg/L; TRIS buffer 50 mmol/L, pH 7.5; preservative.

b) TRIS = Tris(hydroxymethyl)aminomethane

TOXOIGG Cal1 Negative calibrator 1, 1 bottle of 1.0 mL:
Human serum, non-reactive for anti-*Toxoplasma* IgG; buffer; preservative.

TOXOIGG Cal2 Positive calibrator 2, 1 bottle of 1.0 mL:
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.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

All human material should be considered potentially infectious.

The calibrators (TOXOIGG Cal1, TOXOIGG 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 (TOXOIGG Cal2) was sterile filtrated.

The testing methods used assays approved by the FDA 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.^{10,11}

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

Reagent handling

The reagents (M, R1, R2) in the kit are ready-for-use and are supplied in **cobas e** packs.

Calibrators:

The calibrators are supplied ready-for-use in bottles compatible with the system.

Unless the entire volume is necessary for calibration on the analyzer, 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 available via the **cobas** link.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the **cobas e** pack **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the cobas e pack:	
unopened at 2-8 °C	up to the stated expiration date
on the analyzers	16 weeks

Stability of the calibrators:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	16 weeks
on the analyzers 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

Specimen collected from living patients, blood donors, or individual organ, tissue or cell donors may be used, including donor samples obtained while the donor's heart is still beating.

Performance for the use of cadaveric blood specimens (specimens collected post-mortem, non-heart-beating) was established according to Paul-Ehrlich-Institut recommendation¹² with samples obtained within 24 hours after death.¹³ Qualitative differences of neat (non-reactive) or spiked (reactive) specimens from cadaveric compared to living donors were not observed.

Criterion: Mean value of cadaveric specimens compared to specimens from living donors within a recovery of 75-125 %.

Only the specimens listed below were tested and found acceptable. Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin, K₂-EDTA, K₃-EDTA and Na-citrate plasma.

Plasma tubes containing separating gel can be used.

Criterion: Slope 0.9-1.1 + intercept within ± 0.5 IU/mL + coefficient of correlation ≥ 0.95 .

Stability:

For living patients and donor specimens obtained while the donor's heart is still beating: Stable for 3 days at 20-25 °C, 21 days at 2-8 °C, 3 months at -20 °C (± 5 °C). The samples may be frozen 6 times.

For cadaveric specimens: Stable for 1 day at 20-25 °C, 7 days at 2-8 °C. The samples may be frozen 3 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 (e.g. biocides, anti-oxidants or substances that could possibly change the pH or ionic strength 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 thawed 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 and calibrators are at 20-25 °C prior to measurement.

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

Materials provided

See "Reagents – working solutions" section for reagents.

- 2 x 6 bottle labels

Materials required (but not provided)

- [REF] 04618823190, PreciControl Toxo IgG, 16 x 1.0 mL
 - [REF] 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
 - [REF] 07299001190, Diluent Universal, 36 mL sample diluent
 - General laboratory equipment
 - cobas e** analyzer
- Additional materials for **cobas e** 402 and **cobas e** 801 analyzers:
- [REF] 06908799190, ProCell II M, 2 x 2 L system solution
 - [REF] 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
 - [REF] 07485409001, Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
 - [REF] 06908853190, PreClean II M, 2 x 2 L wash solution
 - [REF] 05694302001, Assay Tip/Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
 - [REF] 07485425001, Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning Detection Unit
 - [REF] 07485433001, PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
 - [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.

Elecsys Toxo IgG

Place the cooled (stored at 2-8 °C) **cobas e** pack on the reagent manager. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the **cobas e** pack.

Calibrators:

Place the calibrators in the sample zone.

Read in all the information necessary for calibrating the assay.

Calibration

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

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

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

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Renewed calibration is recommended as follows:

- after 12 weeks when using the same reagent lot
- after 28 days when using the same **cobas e** pack on the analyzer
- as required: e.g. quality control findings outside the defined limits

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 **cobas e** pack, 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:

Numeric result	Result message	Interpretation/ further steps
< 1 IU/mL	Non-reactive	Negative for IgG antibodies to <i>T. gondii</i> .
≥ 1 to < 3 IU/mL	Borderline	Sample should be retested. In case the result is still borderline, a second sample should be collected (e.g. within 3 weeks) and testing should be repeated.*
≥ 3 IU/mL	Reactive	Positive for IgG antibodies to <i>T. gondii</i> and thus indicates either acute or latent infection. Toxo IgM test should be performed to exclude early Toxoplasma infection.*

* Samples with Toxo IgG concentrations ≥ 3 IU/mL to < 30 IU/mL and a negative Toxo IgM 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.

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

Numeric result	Result message	Interpretation/ further steps
< 1 IU/mL	Non-reactive	Negative for IgG antibodies to <i>T. gondii</i> .
≥ 1 to < 30 IU/mL	Borderline	Sample should be retested. In case the result is still borderline a second sample should be collected (e.g. within 3 weeks) and testing should be repeated.*
≥ 30 IU/mL	Reactive	Positive for IgG antibodies to <i>T. gondii</i> and thus indicates either acute or latent infection.

* A persistent concentration between 1 IU/mL and < 30 IU/mL should be considered as borderline and a serological follow-up should be done.

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: A *borderline* 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

The effect of the following endogenous substances and pharmaceutical compounds on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 1129 μmol/L or ≤ 66 mg/dL
Hemoglobin	≤ 0.62 mmol/L or ≤ 1000 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 287 nmol/L or ≤ 70 ng/mL
Rheumatoid factors	≤ 1200 IU/mL
Albumin	≤ 7.0 g/dL
IgG	≤ 7.0 g/dL
IgA	≤ 1.6 g/dL
IgM	≤ 1.0 g/dL

Criterion: For concentrations < 3.0 IU/mL the deviation is ≤ 0.3 IU/mL. For concentrations ≥ 3.0 IU/mL the deviation is ≤ ± 20 %.

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

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.

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.

Pharmaceutical substances

In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found.

In addition, the following special drugs used in Toxoplasmosis therapy during pregnancy were tested. No interference with the assay was found.

Special drugs

Drug	Concentration tested mg/L
Spiramycine	≤ 3000
Sulfadiazine	≤ 2500
Pyrimethamine	≤ 500
Folinic acid	≤ 3

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

0.18-650 IU/mL (defined by the Limit of Detection and the maximum of the master curve). Values below the Limit of Detection are reported as < 0.18 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

Limit of Blank and Limit of Detection

An internal study was performed based on guidance from the CLSI protocol EP17-A2. Limit of Blank and Limit of Detection were determined to be the following:

Limit of Blank = 0.10 IU/mL

Limit of Detection = 0.18 IU/mL

The Limit of Blank is the 95th percentile value from $n \geq 60$ measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

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 analyzers or manually). The concentration of the diluted sample must be ≥ 3 IU/mL.

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

After dilution by the analyzers, the 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, samples and controls in a protocol (EP05-A3) of the CLSI (Clinical and Laboratory Standards Institute): 2 runs per day in duplicate each for 21 days ($n = 84$). The following results were obtained:

cobas e 402 and cobas e 801 analyzers					
Sample	Mean IU/mL	Repeatability		Intermediate precision	
		SD IU/mL	CV %	SD IU/mL	CV %
HS ^{c)} , negative	0.585	0.034	5.8	0.045	7.7
HS, positive	21.8	0.380	1.7	0.586	2.7
HS, positive	324	8.49	2.6	12.2	3.8
PC ^{d)} Toxo IgG 1	1.19	0.044	3.7	0.056	4.7
PC Toxo IgG 2	46.6	0.590	1.3	1.04	2.2

c) HS = human serum

d) PC = PreciControl

Method comparison

a) A comparison of the Elecsys Toxo IgG assay, [REF] 07028008190 (cobas e 801 analyzer; y) with the Elecsys Toxo IgG assay, [REF] 04618815190 (cobas e 601 analyzer; x) gave the following correlations (IU/mL):

Number of samples measured: 210

Passing/Bablok¹⁴ Linear regression

$y = 1.01x - 0.000$

$y = 1.02x - 1.03$

$t = 0.979$

$r = 0.999$

The sample concentrations were between 0.000 and 620 IU/mL.

b) A comparison of the Elecsys Toxo IgG assay, [REF] 07028008190 (cobas e 402 analyzer; y) with the Elecsys Toxo IgG assay,

Elecsys Toxo IgG

[REF] 07028008190 (cobas e 801 analyzer; x) gave the following correlations (IU/mL):

Number of samples measured: 212

Passing/Bablok¹⁴

$y = 1.01x - 0.003$

$r = 0.995$

The sample concentrations were between 0.000 and 632 IU/mL.

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

Site	N	Relative sensitivity %	Lower confidence limit %
2	992	100 (317/317)	99.1
3	439	99.5 (191/192)	97.6
4	380	100 (220/220)	98.7
5	391	100 (188/188)	98.4

Site	N	Relative specificity %	Lower confidence limit %
2	992	99.8 (625/626)	99.2
3	439	98.8 (239/242)	96.8
4	380	100 (159/159)	98.1
5	391	99.0 (200/202)	96.9

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.

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*, Parvovirus 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 concordantly positive. 6 samples were found indeterminate either with the Elecsys Toxo IgG assay or the comparison test and were not included in the agreement calculation.

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

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

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. 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.

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For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets 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 (for USA: see dialog.roche.com for definition of symbols used):

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

07028008500V5.0

Elecsys Toxo IgG

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 0123



Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

