TiSENC

Toxoplasma gondii IgG (CLIA) PACKAGE INSERT

[INTENDED USE]

Toxoplasma gondii IgG (CLIA) is a Chemiluminescence Immunoassay test for the quantitative measurement of Toxoplasma gondii IgG antibody (Toxo IgG) in human serum and plasma, which is intended as clinical diagnosis of Toxoplasma infection.
The test must be performed on the ACCRE series analyzers (including ACCRE 6, ACCRE 8, ACCRE 90, ACCRE 100, ACCRE 120, and all other ACCRE series analyzers).

[SUMMARY]

Toxoplasma gondii is widely parasitic in the nucleated cells of humans and animals. The incubation period of Toxoplasma is 1-2 weeks. After human infection with Toxoplasma, specific IgM antibodies appear within the first 2 weeks, peak at 4-8 weeks, then decline and eventually become undetectable, but sometimes can still be detected up to 18 months after acute infection. IgG antibodies rise more slowly, peak after 1-2 months, and can remain at a high level for several months to years. Since the pathogen can be transmitted through the placenta, it can cause the fetus to lose vision and hearing, intellectual and psychomotor development obstruction, epilepsy, hematopoietic abnormalities, hepatosplenomegaly, and even death. Infection in the early stages of pregnancy can lead to severe central nervous system dysfunction in the fetus; infection in the middle stages of pregnancy may lead to fetal hydrocephalus, intellectual or psychological development obstruction, cerebral calcification, etc.; infection in the late stages of pregnancy leads to neonatal retinochoroiditis and other eye, central nervous system dysfunction diseases. Women should be tested for Toxoplasma before pregnancy or in the early stages of pregnancy to prevent Toxoplasma infection, reduce the occurrence of congenital toxoplasmosis, which is very necessary for eugenics and improving the quality of the birth population.

[ASSAY PRINCIPLES]

The Toxoplasma gondii IgG (CLIA) hereinafter also referred to as the "Toxo IgG" is a two-step immunoassay to determine the level of Toxoplasma gondii IgG.
Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent cartridge. All the assay steps are performed automatically by the ACCRE analyzer.
Firstly, pre-diluted sample, sample treatment solution, Toxoplasma antigen coated magnetic particles were mixed thoroughly together, incubating and washing. The second step, alkaline phosphatase-labeled anti-human IgG antibody was added to it, and incubated for immune reaction to form a immune complex; the complex was washed after the end of the reaction. The addition of a substrate triggers a chemiluminescence reaction, the result of which is measured in relative light units (RLUs) by a photomultiplier tube (PMT). The concentration of the substance to be detected in the sample is proportional to the luminescence intensity. Finally, the ACCRE analyzer automatically calculates the result based on the stored calibration curve.

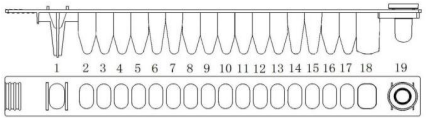
[CONTENT OF THE KIT]

Package: 60 tests/kit with quality controls, 36 tests/kit with quality controls.
Traceability: The calibrator of this kit can be traced back to the the WHO International Standard 13/132. For specific calibrator concentration values, see the Calibrator Barcode Sheet for each lot.

Contents	Quantities		Notice
	REF W302A	REF W302C	
Toxo IgG reagent cartridge	60 strips	36 strips	Ready to use
Toxo IgG Calibrator 1 (CAL 1)	1.0mL× 1 vial	1.0mL× 1 vial	Tris buffer, ProClin300, BND.,Toxo IgG antibody.
Toxo IgG Calibrator 2 (CAL 2)	1.0mL× 1 vial	1.0mL× 1 vial	Tris buffer, ProClin300, BND, Toxo IgG antibody.
Toxo IgG Quality Control level 1 (QC 1)	1.0mL× 1 vial	1.0mL× 1 vial	Tris buffer, ProClin300, BND.
Toxo IgG Quality Control level 2 (QC 2)	1.0mL× 1 vial	1.0mL× 1 vial	Tris buffer, ProClin300, BND, Toxo IgG antibody.
Instruction for Use	1	1	N/A
Reagent Registration Card	1	1	N/A
Calibrator Barcode Sheet	1	1	N/A
Quality Control Sheet	1	1	N/A

Note: Refer to the target value list of the controls from Quality Control Sheet within the kit.

The Reagent Cartridge
The strip consists of 19 wells. The 1st well is the sample well and the last 19th well is the reading well for chemiluminescent signal. From the 2nd to the 18th well are all covered with a labeled, aluminum foil seal. The label comprises a barcode which mainly indicates the reagent assay information, reagent lot number and expiration date. All reagents components needed for the assay are ready-to-use and pre-dispensed in the cartridges. And please do not interchange integral component from different reagents or lots.



Description of the reagent cartridge

Well	Component	Content	Volume
5	Enzyme Label	ALP (alkaline phosphatase) labeled anti-human IgG antibody, MES Buffer, ProClin300, BND.	150μL
7	Magnetic Particles	Toxoplasma antigen coated magnetic particles, Tris buffer, ProClin300, BND.	75μL
9	Sample treatment solution	Tris buffer, ProClin300, BND.	75μL
2,3,10, 11, 12,	Wash Solutions	Tris buffer, ProClin300, BND.	500μL
16	Substrate Solution	Disodium [(4-chlorophenyl)sulfanyl] (10-methyl-9(10H)-acridinylidene) methyl phosphate.	200μL
18	Sample diluent	Sodium chloride	420μL

Note: Well 1,4,6,8,13,14,15,17, are empty.

[MATERIALS AND DISPOSABLES REQUIRED BUT NOT PROVIDED]

• Sample diluent (manufactured by Tisenc).
• Pipette with disposable tip to dispense 200 μL.
• Powderless and disposable gloves.
•Disposable tips for ACCRE analyzer.
• For other specific materials and disposables, please refer to the Instrument User Manual.
• Instruments of the ACCRE series analyzers.

[WARNINGS AND PRECAUTIONS]

• This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest; do not inhale).
• Do not use reagents after the expiration date indicated on the box label.
• Do not use if the packaging of reagent cartridge is damaged or leaked.
• Do not use the reagents if the quantity is obviously insufficient.
• If any component adheres to inside wall of wells or aluminum film of the reagent cartridge, please gently switch the reagent cartridge to let the component back the wells.
• Do not reverse the reagent cartridge. Otherwise, the result will be unreliable.
• Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.
• Use powderless gloves, as powder has been reported to cause false results for certain enzyme immunoassay tests.
• When using this kit, it is important to follow all laboratory reagent handling precautions; skillful technique and strict adherence to the instructions are necessary to obtain reliable results.
• Do not use mixed samples, heat-inactivated samples, or samples that are visibly contaminated with microorganisms.
• Due to methodological or antibody specificity reasons, testing of the same sample with reagents from different manufacturers may yield different results, and results obtained with different reagents should not be compared directly with each other to avoid erroneous medical interpretations; it is recommended that laboratories indicate the characteristics of the reagents used in the test reports sent to clinicians.

[STORAGE]

• Store the Toxoplasma gondii IgG (CLIA) upright at 2-8 °C, kit can be stored for 18 months from manufactured date. After the reagent cartridge is taken out from the refrigerator to equilibrate, the testing should be completed within 2 hours.
• Store the calibrators and quality controls at 2-8 °C till expiry date. When opened, the calibrators and/or controls will be stable for 30 days at 2-8 °C.
• Keep away from sunlight.
• Do not freeze reagents cartridge.

[SAMPLES]

The sample volume for Toxoplasma gondii IgG (CLIA) assay is 30μL, please note that at least 55μL of sample has to be pipetted manually into the reagent cartridge.

Sample type and collection
Human serum or plasma (heparin lithium, heparin sodium, sodium citrate, EDTA-K_2, EDTA-K_3,) are recommended
Types of tubes:
- Plastic tube with clot activator;
- Plastic tube with clot activator and separation gel,
- Plastic tube with heparin lithium,
- Plastic tube with heparin sodium,
- Plastic tube with sodium citrate,
- Plastic tube with EDTA-K_2,
- Plastic tube with EDTA-K_3.

It is recommended to validate collection tubes before using them as some may contain substances which interfere with test results.
Note: Blood sampling tube results may vary from one manufacturer to another depending on the materials and additives used.
It is the responsibility of each laboratory to validate the type of sample tube used and to follow the manufacturer's recommendations for use.

Sample preparation
The current revision of the WHO/DIL/LAB/99.1 document provides recommendations for the preparation of samples. For use of the sample tubes, follow the tube manufacturer's instructions for use.
The pre-analytical step, including the preparation of blood samples, is an essential part of medical analyses. In accordance with Good Laboratory Practice, this step is performed under the responsibility of the laboratory manager.
Insufficient clot time can result in the formation of fibrin with micro-clots that are invisible to the naked eye. The presence of fibrin, red blood cells, or suspended particles

can lead to erroneous results.
Samples containing suspended fibrin particles or erythrocyte stroma should be centrifuged before testing.
If there is a lipid layer over the sample after centrifuging, please transfer the clear sample into a new sample tube without transferring the lipid layer.
Severe hemolysis samples or heat-inactivated samples are not recommended for applying on the reagents.
Preparation of frozen-stored samples: after thawing, these samples must be thoroughly mixed before testing.
Mix using a vortex-type mixer. If necessary, clarify samples by centrifuging before testing.

Sample stability
Samples (serum and plasma) can be stored at room temperature(15-30°C) for up to 8 hours or at 2-8°C for up to 7 days; if longer storage is required, freeze the serum or plasma at -20°C or below -20 °C, without exceeding 3 times freeze/thaw cycle.

[INSTRUCTIONS FOR USE]

For complete instructions, see the Instrument User Manual.
When using the assay for the first time. Register the assay using the registration code in the reagent kit before any assay is used in the ACCRE analyzer for the first time. Calibration, QC and sample test are only available after assay was registered successfully.
When opening a new lot of reagents. Each new lot of reagent must be registered by using the registration code in Reagent Registration Card within the reagent kit.

Calibration
Calibration must be performed with the reagents and calibrators from Manufacturer.
Calibration is necessary under the following conditions:
(1). New reagent lot number applied;
(2). Same lot of reagents used more than 4 weeks;
(3). QC out of control;
(4). When necessary, for example: system maintenance or repair that may affect the analytic performance.

Test Procedure
1. Remove the kit from storage at 2-8 °C and take out the required number of reagent cartridges. Allow the reagent cartridges, specimens, calibrators, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Use each assay strips for each sample, calibrator or control respectively.
3. Place the reagent cartridges into the reagent rack.
4. Manual sample dilution: Use the sample diluent to dilute the sample under test at 1:15 (for example, a 10uL sample is evenly mixed with140uL sample diluent).
Note: the calibrator, control has been pre- diluted and can be used directly.
5. Manually pipette the Sample, Calibrator, or Control into the sample well of each reagent cartridge .
Please note that at least 55µL sample has to be pipetted manually into the reagent cartridge and 30µL sample is needed for each test.
** Before pipetting: Mix the samples using a vortex-type mixer if necessary, and ensure that the samples and sample diluent (if applicable) DO NOT have any bubbles. The same for calibrators and controls.*
6. Put the sample rack into the reagent chamber of ACCRE analyzer.
7. Place the assay tips into the reagent chamber of ACCRE analyzer.
8. Input Sample ID, sample type, dilution etc. into the software as directed by USER MANUAL.
9. Toxoplasma gondii IgG (CLIA) assay will be performed automatically by the ACCRE analyzer.
10. After assay is completed, remove the reagent rack from the ACCRE analyzer. Dispose the used reagent cartridge into an appropriate recipient.

Dilution
Samples with concentrations above 120 IU/mL can be diluted with sample diluent manually. The recommended dilution is 1:10. The concentration of the diluted sample must be >12 IU/mL. After manual dilution, multiply the result by the dilution factor (10x). ACCRE analyzer cannot perform automatic dilution for samples.

Quality control
Quality control should be performed in accordance with local regulations or requirements related to accreditation, as well as requirements defined in the laboratory's quality control procedure.

[RESULTS AND INTERPRETATION]

Calculation of Results
The results are automatically calculated by the ACCRE analyzer using stored calibration curve which generate by 2-point calibration, and calculated according to a predefined mathematical model, the results expressed in IU/mL.

Interpretation of Results
The positive judgment value was determined by receiver operating characteristic curve (ROC) method as follows:
A test result < 0.80IU/mL was judged negative;
0.80 IU/mL≤ a test result < 1.20 IU/mL is considered suspicious;
A test result ≥ 1.20 IU/mL, it is considered positive.
Since there are some differences in different sample groups in different regions, it is recommended that each laboratory establish its own positive judgment value according to the actual situation.
A test result <0.80IU/mL suggests a non-recent infection, but does not exclude the absence of Toxo infection because the time from Toxo infection to antibody production varies from person to person, and it is possible that the body may not have produced enough antibodies to be detected at the time of testing.
0.80 IU/mL≤ a test result < 1.20 IU/mL is considered a suspicious result, and it is recommended to re-sample the test after 1-2 weeks or use other testing methods for confirmation.
A test result ≥ 1.20 IU/mL suggests that the infection may be recent, and it is recommended to combine the results of IgM antibody and IgG antibody affinity test to make a comprehensive judgment.
** Please note that results may differ between laboratories due to variations in population and test method. If necessary, each laboratory should establish its own reference range.*
In interpreting the results, patient's clinical condition including symptoms, diseases history, and other relevant data and information should be considered.

[LIMITATIONS]

1.For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
2. Please note that heterophile antibody in human serum and plasma can interfere the test result.
3. High concentration of HAMA can also cause a false positive or false negative result.
4. If the test results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
5.At the initial stage of infection, Toxo IgG specific antibody did not produce or was lower than the detection limit, which would lead to negative results. If pathogen infection was suspected, the patient should be prompted to review within a period of time. For example, more than 2 weeks, take a second sample, and test it under the same conditions as the first sample, to determine whether there was seroconversion of primary infection or Toxo specific IgG antibody was significantly increased.
6. Toxo IgG is negative, which may occur in the early stage of acute infection of the disease. Negative results should be interpreted in combination with clinical symptoms or pathogen contact, and in combination with other diagnostic testing methods.
7.Patients with impaired immune function or receiving immunosuppressive therapy, such as human immunodeficiency virus (HIV) - infected patients or patients receiving immunosuppressive therapy after organ transplantation, have limited reference value for antibody and antibody avidity testing, which may lead to wrong medical interpretation.
8. people who have received blood transfusion or other blood products in recent months should be cautious in the analysis of their positive test results.

[PERFORMANCE CHARACTERISTICS]

Detection Limit
Limit of Blank (LoB): 0.05 IU/mL
Limit of Detection (LoD):0.1 IU/mL.
The Limit of Blank and Limit of Detection were determined in accordance with the CLSI® EP17-A2 recommendations.

Measurement range
The measurement range is the range of values corresponding to the acceptable performance limits (precision and linearity).
The measurement range of the Toxoplasma gondii IgG (CLIA) assay is 0.8~120 IU/mL.

Linearity
Linearity was evaluated according to CLSI® EP06-A recommendations. The Toxoplasma gondii IgG (CLIA) assay is between 0.8~120.00 IU/mL. The absolute linear correlation coefficient (r) should be greater than 0.9900.

Precision
The precision study was performed according to CLSI® EP05-A3 recommendations.
The within-lot precision CV% is less than 10%.

Accuracy
The relative deviation between the measured value and the calibration concentration is within the range of ±15%.

Interfering Substances
Potential interference substances were studied according to CLSI ® EP07-A3 recommendations.
Total IgG, total IgM, bilirubin, hemoglobin, triglycerides, antinuclear antibodies, rheumatoid factor, HAMA, and common therapeutic drugs (acetylspiramycin, pyrimethamine, sulfadiazine, formyltetrahydrofolate) had no significant effect on the test results.

Cross-reactivity
No cross-reactivity with positive samples for Toxoplasma gondii IgM antibody (Toxo IgM), Cytomegalovirus IgG (CMV IgG), Rubella virus IgG (RV IgG), Herpes simplex virus type I IgG (HSV-1 IgG), herpes simplex virus type II IgG (HSV-2 IgG), EB virus IgG, hepatitis B virus IgG, hepatitis A virus IgG, varicella zoster virus IgG, and Mycoplasma pneumoniae IgG.

[WASTE DISPOSAL]

Dispose used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

[INDEX OF SYMBOLS]

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Consult instructions for use		Contains sufficient for <n> tests		Date of manufacture
	Temperature limit		Use-by date		Do not re-use
	Keep away from sunlight	LOT	Batch code	REF	Catalogue number
	Do not roll		Keep dry		Manufacturer
	Biological risks		Do not use if package is damaged		Contains biological material of animal origin
	Upright		Caution	CONTROL	Control
	Fragile, handle with care				

[REFERENCES]

1. Halonen SK, Weiss LM. Toxoplasmosis. Handb Clin Neurol, 2013;114:125-45.
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3. Stray-Pedersen B. Toxoplasmosis in pregnancy. Baillieres Clin Obstet Gynaecol, 1993,7(1):107-37.

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