

# GBLISA TOXO IgG Kit

Detection of IgG Antibody to Toxoplasma gondii (ELISA)

KIT NAME	KIT SIZE	CAT. NO
GBLISA TOXIO IgG Kit	96T	GBLTOG096T

## Intended Use

Toxoplasma gondii IgG antibody detection kit (enzyme-linked immunosorbent assay) for in vitro qualitative detection of human serum or Toxoplasma IgG antibodies in plasma. Auxiliary diagnosis and immune status for TORCH pathogen infection evaluation of.

## INTRODUCTION

Toxoplasma gondii (Toxoplasma gondii, Tox) is a parasitic opportunity in human and mammalian tissue cells Sexually pathogenic protozoa, which causes toxoplasmosis, a zoonotic disease that is widespread all over the world. Toxoplasma infection in pregnant women can have serious consequences for the fetus. Toxoplasma gondii infection in early pregnancy The fetal malformations caused mainly include: hydrocephalus, cerebellar malformation, chorioretinitis and cerebral calcification. Bloodstream infection can cause necrotizing damage to multiple organs in the fetus, such as hepatosplenomegaly, myocarditis, and thrombocytopenia IgM antibodies are an indicator of recent infection, but only by the detection of IgM antibodies Infection is more difficult because recurrent infections also produce IgM antibodies, and for some immune functions In deficient people, IgM antibodies may exist for more than half a year, so IgM and IgG antibodies are measured at the same time It can be speculated whether the patient has an active infection recently.

## PRINCIPLE

This kit uses enzyme-linked immunosorbent assay to detect Toxoplasma gondii IgG antibody in serum or plasma. in micro The well strips were pre-coated with TOX antigen, reacted with Toxoplasma gondii IgG antibody in the serum, and then added HRP-labeled antibody. Human IgG antibody is combined with it to form an antigen-antibody-enzyme-labeled antibody complex, which is then reacted with TMB Color rendering.

## KIT COMPONENTS

Microplate Wells	1
Enzyme-labeled antibody	1 x 12 ml
Positive control	1 x 1 ml
Negative control	1 x 1 ml
Sample Diluent	1 x 12 ml
Concentrated Wash	2 x 25 ml
TMB substrate	1 x 12 ml
Stop solution	1 x 7 ml

## Storage and Stability

1. Store at 2~8°C away from light, valid for 12 months.
2. After the kit is opened, seal the unused microwell strips with sealing film in time, and put them in together with the desiccant. Self-sealing bag, tighten the lid in time after use of liquid components, and store at 2~8°C.

## Instrument Requirements:

Microplate reader (single wavelength 450nm or dual wavelength 450nm/630nm)

## Sample Collection and Preparation

1. Using human serum or plasma samples, the use of EDTA, heparin, and sodium citrate as anticoagulants will not affect the impact the experimental results.
2. If the serum and plasma samples are tested within 7 days after collection, they can be stored at 2~8°C; more than 7 days It must be stored frozen below -20°C, the storage time should not exceed 1 year, and the repeated freezing and thawing should not exceed 4 times, otherwise will affect the test results. Cryopreserved samples should be completely thawed, rewarmed, and evenly mixed before use.

## Procedure

1. Equilibration: Take the components of the kit out of the box, equilibrate at room temperature for more than 30 minutes, After opening, the rest should be sealed in ziplock bags in time.
2. Dosing: Dilute the concentrated washing solution 20 times with distilled or deionized water.
3. Number: Correspond the sample to the microplate number, each plate should have 3 wells for negative control, 1 well for positive control, Blank control 1 well. (Blank control is not required for dual wavelength detection)
4. Dilution: add 100µl of sample diluent to each well with a dispenser, negative control well, positive control well Except for the blank control wells.
5. Add sample: add 100µl negative, positive control and 10µl sample to be tested to the corresponding wells, tap Mix well.
6. Incubation: Cover with sealing film and incubate at 37°C for 30 minutes.
7. Washing: Carefully remove the sealing film, set it in a plate washer and wash it with washing solution for 5 times, and then press the button after washing. Dry (30-60 seconds of soaking time should be maintained each time).
8. Add enzyme: Add 100µl of enzyme-labeled antibody to each well.
9. Incubation: Cover with sealing film and incubate at 37°C for 30 minutes.
10. Washing: The operation is the same as 7.
11. Color development: Add 100µl of TMB substrate to each well, tap to mix, and incubate at 37°C for 15 minutes.
12. Stop: Add 50µl of stop solution to each well and mix well.
13. Determination: Measure the OD value of each well with a microplate reader at single wavelength 450nm or dual wavelength at 450/630nm. (When using a single wavelength measurement, a blank control hole should be set), complete the measurement within 30 minutes, and record the results.

## INTERPRETATION OF TEST RESULTS

1. Negative control: Under normal circumstances, the OD value of negative control wells is  $\leq 0.10$ . (negative control OD value If the OD value of all negative control wells is greater than 0.10, it should be discarded, and the experiment should be repeated)
2. Positive control: Under normal circumstances, the OD value of the positive control well is  $\geq 0.5$ .
3. Calculation of critical value (C.O.): critical value =  $0.150 + \text{mean value of negative control}$ .
4. Judgment of results: Samples with OD value  $S/C.O. \geq 1$  are Toxo IgG antibody reactive should be positive; samples with OD value  $S/C.O. < 1$  are negative for Toxo IgG antibody.

## DESCRIPTION OF TEST RESULTS

1. For IgG antibody detection gray area samples, it is recommended to perform additional IgM antibody detection or 2 weeks Repeat the test afterwards.

2. A negative sample does not completely rule out the possibility of no infection, because different people go from infection to Depending on the timing of antibody production, there may not be enough antibody produced in the body to be detected at the time of the test.

Suspected infected individuals with negative test results should have their samples retaken in 4-12 weeks; Pregnant women, it is recommended to track the changes in IgG antibodies during pregnancy.

3. There may be false positives in the test results, and suspicious samples need to be re-tested or other testing methods should be used. method to confirm.

4. If the first test result is positive, and the repeat test results are negative, then Confirmatory experiments are required. The result of a non-repeated positive reaction may be due to the following factors:

- a. Cross-contamination due to instrument or pipette tip;
- b. The substrate is contaminated with metal ions;
- c. Insufficient plate washing.

### Limitations:

1. The test results of this product are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical diagnosis of patients should be combined with their symptoms/signs, medical history, epidemiology, other laboratory tests (such as pathogenic Information such as scientific testing) should be considered comprehensively.

2. TOURCH -specific IgG negative, may appear in the early stage of acute infection of the disease, negative results Results should be interpreted in conjunction with clinical symptoms or exposure to pathogens and other diagnostic tests.

3. Immunocompromised or immunosuppressive patients, such as human immunodeficiency virus (HIV) Antibody and antibody avidity test for infected patients or patients receiving immunosuppressive therapy after organ transplantation of limited reference value and may lead to erroneous medical interpretations.

### Performance

The conformity rate of negative reference products is 100%;

The conformity rate of positive reference products is 100%;

Minimum detection limit coincidence rate  $\geq 3/5$

Precision:  $CV \leq 15\%$

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## Genuine Biosystem Private Limited

Plot 97 & 98, Kattabomman street, Parvathy nagar Extn,

Old Perungalatur, Chennai-600063.TN.India

Ph:044-48681845

Email: [info@gb-group.co.in](mailto:info@gb-group.co.in)

Web: [www.genuinebiosystem.com](http://www.genuinebiosystem.com)