GBLISA TOXO IgM Kit

Detection of IgM Antibody to Toxoplasma gondii (ELISA)

GENUINE BIOSYSTEM

KIT NAME	KIT SIZE	CAT. NO
GBLISA TOXIO IgM Kit	96T	GBLTOM096T

Intended Use

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

INTRODUCTION

Toxophasma gondii is distributed worldwide and has a wide range of hosts. Felines are Its ultimate host, humans and many vertebrates are its intermediate hosts, which can cause zoonotic oxoplasmosis (toxoplasmosis). Toxoplasmosis is distributed all over the world and is not limited by climate and geographical location. The situation varies from place to place. According to serological survey data, the infection rate of the Chinese population is 4.0% to 9.0%. The infection rate of women is as high as 6.6% to 32.9%. Toxoplasma-specific IgM antibodies can be detected 5 to 7 days after Toxoplasma infection, and maintained Weeks to months, disappear within 3 to 9 months. Specific IgG antibodies are usually produced in IgM antibodies Appears after about a week, then rises rapidly and stabilizes at a higher titer for a longer period of time. Bow Plasmodium-specific IgM antibodies are positive for early infection.

PRINCIPLE

This kit uses enzyme-linked immunosorbent assay to detect Toxoplasma gondii IgM antibody in serum or plasma. in micro The well strips were pre-coated with TOXO antigen, reacted with Toxoplasma gondii IgM antibody in the serum, and then added HRP-labeled antibody. Human IgM 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℃.

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 ≤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 ≥0.5.
3. Calculation of critical value (C.O.): critical value=0.150+mean value of negative control.
4. Judgment of results: Samples with OD value S/C.O.≥1 are Toxo IgM antibody reactive should be positive; samples with OD value S/C.O.<1 are negative for Toxo IgM antibody.

DESCRIPTON OF TEST REULTS

1. In the early stage of infection, IgM antibody is not produced or the titer is lower than the minimum detection limit will lead to a negative result, should be referred. Instruct the patient to re-examine within

7-14 days, and test the last collected specimen in parallel during the re-examination to confirm whether the Seroconversion or IgM antibody titer is significantly increased;
2. For patients with impaired immune function or receiving immunosuppressive therapy, the reference value of serological antibody detection limited value;
3. IgM antibody positivity occurs not only in primary infection, but also in secondary infection;
4. Unreasonable sample collection, transportation and processing, and low IgM antibody titers in the sample are all possible lead to false negative results;
5. Other unverified interfering factors, such as drug abuse, may lead to false negative results;
6. If the first test result is positive, and the repeat test results are negative, you need to
Carry out a confirmation experiment. 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. All highly sensitive immunoassays may have non-specific reactions.
2. A negative result does not rule out exposure or infection with Toxoplasma gondii.
3. The positive result of IgM antibody to Toxoplasma gondii should be combined with the clinical history and other test results. Judgment should not be used as the sole basis for early diagnosis of Toxoplasma gondii infection.
4. 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 (e.g. etiology)
detection) and other information comprehensively considered.
5. Due to the high prevalence of laboratory tests for Toxoplasma gondii (TOX)-specific IgM antibodies in pregnant women There is a risk of false positives, and the risk of fetal disease cannot be reliably identified, so bowing is not recommended for asymptomatic pregnant women.
Organozoites (TOX) IgM Antibody Screening. The test results of this reagent should not be used as the basis for termination of pregnancy alone.
6. Positive test for people who have received blood transfusion or other blood product treatment in recent months The analysis of the results should be done with caution.
7. When a positive result of TOX-IgM is detected in an asymptomatic population in a low prevalence area, alert Be wary of possible false positive results. It is also recommended that clinicians combine their symptoms/signs, medical history, current
Epidemiology, other laboratory tests (such as IgG antibody affinity and etiological testing) to judge.
8. Heterophilic antibodies in human serum may interfere with the test results by binding to immunoglobulins in the reagents. People who frequently come into contact with animals or animal serum products should be alert to possible abnormal interference results.
9. Patient samples treated with mouse monoclonal antibodies may contain human anti-mouse antibodies (human anti-mouse antibodies, HAMA), if the sample to be tested contains HAMA, it will affect the detection the accuracy of the test results.

PERFORMANCE

The conformity rate of negative reference products is 100%;
The conformity rate of positive reference products is 100%;
Minimum detection limit coincidence rate ≥ 3/5
Precision: CV≤15%

PRECAUTIONS

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. ToRCH-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.

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