InTec PRODUCTS, INC.

Combined Test Kit for Anti-Toxoplamosis (IgM/IgG), Anti-Cytomegalovirus (IgM/IgG), Anti-Rubella virus IgG (Colloidal Gold) Instructions for Use

ITP62001-TC25
01.05.03.1442-220302

[Intended Use]

The kit is intended to qualitatively detect Toxoplasma IgM, Toxoplasma IgG, Cytomegaloviru IgM, Cytomegaloviru IgG and Rubella virus IgG in human serum, plasma or whole blood in vitro. It is suitable for clinical auxiliary diagnosis of Toxoplasma infection, Cytomegalovirus infection and Rubella virus infection as well as their epidemiological investigation and diagnosis.

The word TORCH is a combination of the first letters of English names of several pathogens that can cause intrauterine embryo (fetal) infections, miscarriages, and even birth defects or developmental abnormalities in pregnant women. It includes Toxoplasma (TOX), Cytomegalovirus (CMV), Rubella virus (RV) and Herpes Simplex virus (HSV). TORCH infection is a teratogenic microorganism with a high incidence that can cause miscarriage of pregnant women and fetal malformation.

Specific IgM antibody detected after TORCH infection indicates that the patient has recently been infected, and IgM antibody can also be detected when latent virus is activated to produce recurrent infection. IgG antibody titers rise within 1-2 weeks and can last for several years, with certain immunity. Testing for TORCH-IgG can indicate whether a patient has had a previous infection or whether immunization is needed.

[Test Principle]

The kit adopts highly specific antigen-antibody reaction and immunochromatographic analysis technology, and qualitatively detects whether human serum, plasma or whole blood contain TOX-IgM, TOX-IgG, CMV-IgM, CMV-IgG and RV-IgG by the test principle of capturing-ELISA and indirect-ELISA methods.

Where:

TOX-IgM: A mouse anti-human IgM monoclonal antibody was coated on the nitrocellulose membrane at the test line (T), a goat anti-chicken IgY was coated at the control line (C), and a colloidal gold-conjugated TOX recombinant antigen and chicken IgY were fixed on the conjugate pad;

TOX-IgG: A mouse anti-human IgG monoclonal antibody was coated on the nitrocellulose membrane at the test line (T), a goat anti-chicken IgY was coated at the control line (C), and a colloidal gold-conjugated TOX recombinant antigen and chicken IgY were fixed on the conjugate pad;

CMV-IgM: A mouse anti-human IgM monoclonal antibody was coated on the nitrocellulose membrane at the test line (T), a goat anti-chicken IgY was coated at the control line (C), and a colloidal gold-conjugated recombinant antigen of Cytomegalovirus and chicken IgY were fixed on the conjugate pad;

CMV-IgG: A cytomegaloviru recombinants antigen was coated on the nitrocellulose membrane at the test line (T), a goat anti-chicken IgY was coated at the control line (C), and a colloidal gold-conjugated mouse anti-human IgG monoclonal antibody and chicken IgY were fixed on the conjugate pad;

RV-IgG: A rubella virus recombinant antigen was coated on the nitrocellulose membrane at the test line (T), a goat anti-chicken IgY was coated at the control line (C), and a colloidal gold-conjugated mouse anti-human IgG monoclonal antibody and chicken IgY were fixed on the conjugate pad;

When testing, antibodies in the samples, such as TOX-IgM/IgG, CMV-IgM/IgG and RV-IgG, can specifically bind with the gold-conjugated substances on each conjugate pad to form an immune complex, . The immune complex will then move forward along the test strip.If positive, the complex will be captured by the coated substance at the test line (T), forming a visible red band. If negative, there is no red band at the test line(T). No matter whether there are TOX-IgM/IgG, CMV-IgM/IgG or RV-IgG in the sample, the colloidal gold-conjugated chicken IgY will be captured by the goat anti-chicken IgY at the control line (C) and a red band appears at the control line (C). Only when the control line appears, the correlated result is valid..

[Reagent and materials provided]

FOR CARD TEST, ITP62001-TC25:

1. Test cards individually foil pouched with a desiccant.....25
2. Pipettes.....25
3. Buffer bottles.....2
4. Instructions for use.....1

Note: Components of reagents with different lot numbers cannot be mixed.

[Materials required but not provided]

1. Timer
2. Sample collection container
3. Disposable gloves

[Storage conditions and stability]

1. Storage:store at 2~30℃.
2. Shelf life: 24 months.
3. The test cassette should be used as soon as possible within 1h after being taken out of the foil pouch, and should be ready to use in case the air humidity is greater than 70%.

[Sample Preparation]

1. It is only applicable to human serum, plasma or whole blood, and other body fluids and samples may not get accurate results.
2. Commonly used anticoagulants (EDTA, heparin, sodium citrate) do not affect the test results.
3. Hemolytic, fatty, bacterial, overly viscous, or other contaminated samples are not suitable for this kit.
4. The samples should be collected and tested immediately. If testing can't be done after sample collection, the serum or plasma could be stored at 2-8℃ up to 7 days and should be frozen at -20℃ or below for long-term storage. Whole blood samples that cannot be tested in time should be stored at 2-8℃, and tested within 7days without freezing.
5. Before testing, the samples and test reagents should be slowly returned to room temperature. Frozen samples should be completely melted,and mixed evenly before being used. Repeated freezing and thawing should be avoided.

[Test Procedure]

Please read the instructions for use first before testing, and bring the required reagents and samples to room temperature prior to testing. Remove the test cassette from the sealed pouch, place it on a flat, clean and dry surface.

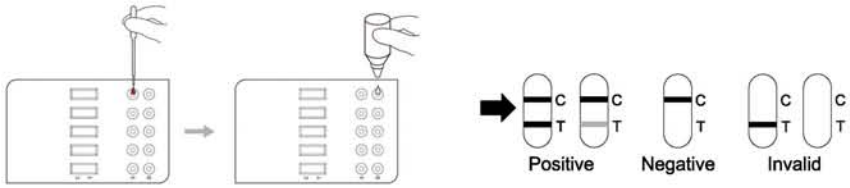
Test cassette:

1. Serum/plasma sample: Hold a pipette vertically and draw 1 drop (or 10 μL) of serum or plasma sample into the sample well (S) on the test cassette, and immediately add 2 drops (about 80 μL) of buffer vertically into the dilution well (D) on the test cassette.

Whole blood sample: Hold a pipette vertically and draw 2 drops (or 20 μL) of the whole blood sample into the sample well (S) on the test cassette, and immediately add 2 drops (about 80 μL) of buffer vertically into the dilution well (D) on the test cassette.

2. Read the results within 15-20 minutes, otherwise the results are invalid.

10 uL serum/plasma sample or 20 uL whole blood sample **2 drops of buffer**



[Interpretation of Test Results]

Positive: Two red bands appear, the lower one is the test line (T) and the upper one is the control line (C), it means the presence of detectable TOX, CMV, RV-IgM or IgG in the samples. Other clinical indicators should be combined to determine whether the patient has been infected with TOX, CMV or RV and whether it is an acute infection.

Negative: Only one red band appears at the control line (C), but no red band at the test line (T), it means that there are no TOX, CMV, RV-IgM or IgG in the samples, or the antibody level is lower than the limit of detection. Despite a negative result, the possibility of infection can not be ruled out.

Invalid: No red band is observed at the control line (C). The direction may not been followed correctly or the test may be deteriorated. It is recommended that read again the instructions carefully, and repeat the test using a new device. If the problem repeats, stop using this batch of products immediately and contact local suppliers.

[Interpretation of Test Results]

Note: The red band of the test line may show the phenomenon of color depth. However, within the specified observation time, as long as there is a red band at the control line (C), no matter the color of the test line (T), even if only a very weak band should also be judged as positive results.

[Limitations of Test]

1. The kit is suitable for qualitative detection of TOX-IgM, TOX-IgG, CMV-IgM, CMV-IgG and RV-IgG in human serum, plasma or whole blood in vitro, and the exact content cannot be determined.
2. At the initial stage of infection, the absence of IgM or very low titers will result in a negative result. Patients should be prompted to reexamine within 7-14 days, with previous samples tested in parallel to confirm positive serological changes or significantly elevated titers.
3. This kit has limited clinical reference value for patients with impaired immune function or receiving immunosuppressive therapy.
4. IgM antibody positive occurs in primary infections, and IgM responses are also observed in secondary infections.
5. The results of this kit are for clinical reference only, and should not be used as the only basis for clinical diagnosis and treatment. The negative test result does not rule out clinical infection, which may be caused by the antibody concentration in the sample being lower than the sensitivity of the product. For suspected negative results, other methodologies with higher sensitivity are recommended for review. Samples with positive test results should be rechecked and confirmed by different methodologies, and virus infection should be comprehensively judged according to the patient's clinical history, symptoms and other diagnostic results.
6. In view of the fact that the laboratory examination of pregnant women cannot reliably identify the risk of fetal disease, screening for asymptomatic maternal infection with this reagent is not recommended and the results of this reagent alone should not be used as a basis for terminating a pregnancy.

[Performance Characteristics]

1. Limit of detection:

The Combined Test Kit can detect the TOX-IgG with concentration≥5 IU/mL, CMV-IgG with concentration≥4 IU/mL RV-IgG with concentration≥10 IU/mL. .

2. Interference

342.0 μmol/L bilirubin, 28.2 mmol/L triglyceride, 5.0 g/L hemoglobin and 20.7 mmol/L cholesterol have no interference with the test results and can be used for sample testing. High concentration of antinuclear antibody, anti-mitochondrial antibody sample, rheumatoid factor (80 IU/mL) and immunoglobulin (10 mg/mL) do not interfere with this test kit.

3. Cross-reactivity

The kit has no significant cross-reactivity with the samples of other TORCH pathogens, EB virus, HIV, Treponema pallidum, Hepatitis B virus, Hepatitis A virus, Influenza A virus, Influenza B virus, Parainfluenza virus and Mycoplasma pneumoniae.

4. HOOK effect

No hook effect can be observed when using this kit to detect TORCH specific antibody at high concentration.

5. Clinical study

A clinical study using a total 2000 blood samples was conducted. The results of the Combined Test kit were compared with EIA kit for TOX-IgM/IgG, CMV-IgM/IgG, RV-IgG. The diagnostic sensitivity and specificity of the test results are given as below:

Table1-Comparison of TOX-IgM EIA kit

Reference		TOX-IgM EIA kit		Total Results
		Positive	Negative	
Results of InTec test	Positive	132	1	133
	Negative	3	264	267
Total Results		135	265	400

Results gave a sensitivity is 97.8% (132/135), a specificity is 99.6% (264/265), and a total agreement of 99% (396/400).

Table2-Comparison of TOX-IgG EIA kit

Reference		TOX-IgG EIA kit		Total Results
		Positive	Negative	
Results of InTec test	Positive	133	3	136
	Negative	5	259	264
Total Results		138	262	400

Results gave a sensitivity is 96.4% (133/138), a specificity is 98.8% (259/262), and a total agreement of 98% (392/400).

Table3-Comparison of CMV-IgM EIA kit

Reference		CMV-IgM EIA kit		Total Results
		Positive	Negative	
Results of InTec test	Positive	194	2	196
	Negative	4	200	204
Total Results		198	202	400

Results gave a sensitivity is 98% (194/198), a specificity is 99% (200/202), and a total agreement of 98.5% (394/400).

Table4-Comparison of CMV-IgG EIA kit

Reference		CMV-IgG EIA kit		Total Results
		Positive	Negative	
Results of InTec test	Positive	252	2	254
	Negative	3	143	146
Total Results		255	145	400

Results gave a sensitivity is 98.8% (252/255), a specificity is 98.6% (143/145), and a total agreement of 98.7% (395/400).

Table5-Comparison of RV-IgG EIA kit

Reference		RV-IgG EIA kit		Total Results
		Positive	Negative	
Results of InTec test	Positive	247	0	247
	Negative	3	150	153
Total Results		250	150	400

Results gave a sensitivity is 98.8% (247/250), a specificity is 100% (150/150), and a total agreement of 99.2% (397/400).

[Precautions]

1. This kit is only used to detect TOX-IgM, TOX-IgG, CMV-IgM, CMV-IgG and RV-IgG in samples, and provides a preliminary analysis result.
2. The test environment should be kept at a certain temperature and humidity, sheltering from wind, and avoiding testing at too high a temperature. Refer to the unsealing stability requirements of the above reagents.
3. This kit can be stored at room temperature and should be protected from moisture. Kit stored at low temperature should be balanced to room temperature prior to use.
4. The test samples waste liquid and wastes should be treated as infectious substances, and attention should be paid to the biological safety of operation. Desiccant in aluminum foil bags should not be taken orally.
5. No certain connection can be found between the depth of the color band at the test line and the titer of the analyte in the samples.
6. This kit is disposable, do not use it after the expiration date.

[References]

[1] Grangeot-Keros L, Mayaux MJ, Lebon P, Eugene G, et al. Value of Cytomegalovirus (CMV) IgG Avidity Index for the Diagnosis of Primary CMV Infection in Pregnant Women[J]. Journal of Infection Diseases, 1997, 175(4):944-946.

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InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022, Xiamen, Fujian, P.R. China
Tel: +86 592 6807188
Website: www.intecasi.com
Email: intecproducts@asintec.com