FRENOVO

ToRCH IgG/IgM Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO ToRCH IgG/IgM Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO ToRCH IgG/IgM Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of IgM & IgG antibodies to Toxoplasma gondii (Toxo), Rubella virus (Rubella), Cytomegalovirus (CMV), and Herpes simplex virus 1/2 (HSV 1/2) in serum, plasma and whole blood specimen to aid in the diagnosis of ToRCH.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

ToRCH is an acronym for a group of infectious diseases, while infecting the pregnant women, may cause birth defects in their newborns. ToRCH stands for four different infections that can adversely affect a pregnant woman and the fetus or newborn often leading to abortion. The infections usually cause few, if any, symptoms in the pregnant woman, but pose greater risks of serious birth defects for neonates. Infections caused by ToRCH is the major cause of BOH (Bad Obstetric History). Risks are severe if the mother gets the infection in the first trimester as the baby's organs start to form in this stage. General symptoms include premature birth, growth retardation, neurological abnormalities, and damage of the eye, liver, heart and ear as well as bone lesions. Microcephaly, hydrocephaly, seizures and psychomotor retardation accompany these malformations.

T.gondii is an obligate intracellular protozoan parasite with a worldwide distribution. Infection with T. gondii is asymptomatic in the majority (80-90%) of cases. The most common clinical manifestation of acute toxoplasmosis in the adult is asymptomatic lymphadenopathy involving single or multiple nodes. Lymphadenopathy may be accompanied by fever, malaise, and atypical lymphocytosis symptoms that mimic infectious mononucleosis. Very rarely will more serious complications, such as encephalitis, myocarditis or pneumonitis, be seen in the normal host. During infection of a seronegative woman with T. gondii during pregnancy, transmission of the organism occurs across the placenta to the fetus. The severity of infection in the fetus varies with the trimester during which the acquisition of the infection occurred. Infection during the first trimester may lead to spontaneous abortion, stillbirth, or overt disease in the neonate. Infection acquired later during pregnancy is usually asymptomatic in the neonate, and may not be recognized. Varieties of serologic tests for antibodies to T. gondii have been used as an aid in diagnosis of acute infection, and to assess previous exposure to the organism. The more widely used tests include the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence, ELISA and PCR.

Rubella is a mild, contagious viral infection that occurs primarily in children and young adults. An erythematous maculopapular rash that lasts two or three days characterizes rubella. However, greater than 50% of rubella infections are not clinically apparent. Other symptoms of rubella may include low-grade fever, mild upper respiratory symptoms, and suboccipital lymphadenopathy. Transient arthralgia and arthritis are common symptoms in young adults but more severe complications such as encephalitis or thrombocytopenic purpura are uncommon. Although rubella infection is usually self-limiting, infection of the fetus during the first trimester may cause spontaneous abortion, stillbirth or congenital birth defects. Congenital rubella syndrome has long been recognized and is characterized by congenital heart disease, cataracts, neurosensory deafness, mental retardation, and intrauterine growth retardation. Following an epidemic of rubella in 1964, new clinical manifestations of congenital rubella were recognized. They included neonatal thrombocytopenic purpura, hepatitis, bone lesions and meningoencephalitis. In addition, diabetes mellitus and progressive rubella panencephalitis are late-emerging manifestations of congenital rubella infection that have recently been recognized. Rubella is endemic worldwide. In countries without vaccination programs, 10-25% of women of childbearing age are seronegative and susceptible to infection. Extensive vaccination programs in the United States and the United Kingdom have greatly reduced the incidence of congenital rubella syndrome. Currently, reports show fewer than 10 cases per year in the United States. The presence of circulating maternal antibody indicates immunity to rubella.

Cytomegalovirus (CMV) infections are widespread and usually asymptomatic; however, the virus may persist as a latent or chronic infection. The relatively frequent incidence and often-severe disease in newborns and immunosuppressed individuals clearly establishes this agent as an important human pathogen. CMV infections can be classified as follows: Congenital - Acquired before birth Perinatal - Acquired at birth Postnatal - Acquired after birth Acquisition of postnatal CMV infections occurs through close contact with individuals who are shedding the virus. CMV has been isolated from saliva, urine, breast milk, cervical secretions, and semen. Consequently, the transmission of the virus may occur through a variety of mechanisms. Sexual transmission of the virus appears to contribute to the acquisition of the virus by young adults. Although the age at which CMV infection is acquired varies with socioeconomic conditions, only about 10 - 15% of children in the United States are seropositive. By age 35 however, about 50% of the population is seropositive. The majority of individuals contracting postnatal CMV infections remain asymptomatic. A small percentage of individuals will develop a negative heterophile antibody infectious mononucleosis syndrome. Characteristics of CMV mononucleosis are fever, lethargy, and atypical lymphocytosis; whereas, in Epstein-Barr virus induced infectious mononucleosis, pharyngitis, lymphadenopathy, and splenomegaly are the chief clinical features. Serologic procedures, which measure IgG antibodies to CMV, can aid in the diagnosis of CMV infection when seroconversion can be demonstrated.

Herpes Simplex Virus (HSV) infections are caused by two distinct types of HSV; HSV-1 and HSV-2. Both HSV types are common human pathogens. HSV-1 is usually associated with infections in the oropharyngeal area and eyes while HSV-2 causes most genital infections. However, HSV-2 can be isolated occasionally from the oropharyngeal area and 15 to 20% of primary genital infections may be caused by HSV-1. HSV infections are transmitted by virus-containing secretions through close personal contact. HSV infections, both primary and recurrent are often sub-clinical and asymptomatic. Shedding of the virus is the most important factor contributing to the spread of the virus. The most severe complication of genital HSV infection is neonatal disease. Of mothers with an active primary infection, the risk of transmission to infants is as high as 40%. About 69 - 80% of infants who develop neonatal herpes are born to women who are asymptomatic of genital HSV infection at the time of birth. Genital herpes is problematic in sexually active adults as well as the disease is often transmitted in the absence of symptoms. HSV antibody testing is indicated for sexually active adults to identify those at risk for acquiring HSV or transmitting HSV to others and for expectant mothers who are at risk for acquiring HSV infections and transmitting neonatal herpes. Although culture combined with direct fluorescent antibody (DFA) testing is definitive in making a diagnosis, the timing is critical and cultures must be obtained during periods of active disease to produce optimal recovery. Serological procedures may be useful for determining evidence of infection with HSV. Many existing serologic methods for determining HSV sero-status, however, are unable to differentiate between HSV-1 and HSV-2 infections. Development of HSV type-specific serological assays occurred using the significant difference between the gG-1 protein of HSV-1 and the gG-2 protein of HSV-2. There are benefits to early application of type-specific serologic testing for HSV-1 and HSV-2 in testing first time, recurrent, and asymptomatic infections to aid in diagnosis and appropriate patient counseling. Type-specific testing is recommended for sexually active adults and pregnant women.

FRENOVO ToRCH IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. In this test, mouse anti-human IgM and IgG are coated in the test line regions of the test. During testing, the serum, plasma or whole blood specimens react with ToRCH antigen-coated gold particles in the label pad. The mixture then migrates forward on the membrane by capillary action and reacts with the mouse antihuman IgM and IgG on the membrane in the test line regions respectively. The presence of a colored line in the test line (G) region indicates a positive result for ToRCH antibody IgG, the presence of a colored line in the test line (M) region indicates a positive result for ToRCH antibody IgM, while any absence indicate a negative result for that infection.To serve as a procedural control, a coloured line will always appear in the control reaction zone (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 25 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 5 pieces dropper bottle with 3.0 ml solution filled each bottle.
3. Droppers: 25 pieces droppers of 10 ul.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micro-pipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kits for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO ToRCH IgG/IgM Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test cassettes from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples: Whole Blood/Serum/Plasma.
2. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected as soon as possible. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
8. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

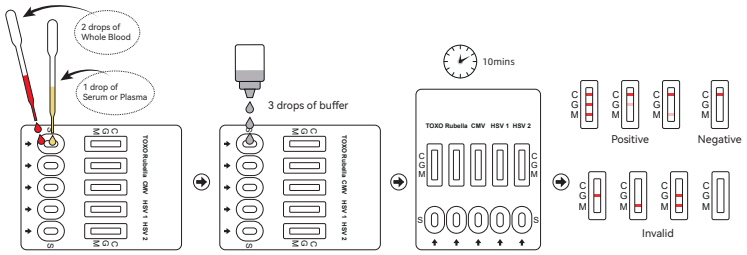
Allow the test cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.

2. For Serum or Plasma Specimens
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 10ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution(approximately 90ul) inside to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution (approximately 90ul) inside to the sample well and start the timer.
For Whole Blood Specimens
To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 20ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution(approximately 90ul) inside to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
To use a micro-pipette: Pipette and dispense 20ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution (approximately 90ul) inside to the sample well and start the timer.

3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

IgG and IgM POSITIVE: Three lines appear. One colored line should be in the control line region (C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. the result is positive for IgG & IgM antibodies and is indicative of secondary ToRCH infection.

IgG POSITIVE: Two lines appear. One colored line should be in the control line region(C), and a colored line appears in IgG test line region. The result is positive for ToRCH specific-IgG and is probably indicative of secondary ToRCH infection.

IgM POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for ToRCH specific-IgM antibodies and is indicative of primary ToRCH infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of ToRCH antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive.

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The kit is for in vitro diagnostic use only. The test should be used for the detection of ToRCH IgG/IgM antibodies in serum, plasma or whole blood specimens only.
2. FRENOVO ToRCH IgG/IgM Rapid Test Kit will only indicate the presence of IgM&IgG antibodies to Toxo, Rubella, CMV and HSV 1/2 in the specimen and should not be used as the sole criteria for the diagnosis of ToRCH infections for which the positive result is obtained.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result for any one out of the four infections of ToRCH at any time does not preclude the possibility of that particular infection.Results from this test should not be used to diagnose or to exclude acute ToRCH infection or to inform infection status.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
Clinical study was performed to compare the results obtained by The kit and PCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

TOXO IgM Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	71	7	78
	Negative	2	674	676
Total Results		73	681	754

TOXO IgM Study Summary Results: Clinical sensitivity =97.26% (95%CI*90.45% ~ 99.67%)
Clinical specificity =98.97% (95%CI*97.89% ~ 99.59%) Accuracy=98.81% (95%CI*97.75% ~ 99.45%)

TOXO IgG Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	68	6	74
	Negative	3	675	678
Total Results		71	681	752

TOXO IgG Study Summary Results: Clinical sensitivity =95.77% (95%CI*88.14% ~ 99.12%)
Clinical specificity=99.12% (95%CI*98.09% ~ 99.68%) Accuracy=98.80% (95%CI*97.74% ~ 99.45%)

Rubella IgM Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	36	2	38
	Negative	0	356	356
Total Results		36	358	394

Rubella IgM Study Summary Results: Clinical sensitivity >99.00% (95%CI*92.02% ~ 100.0%)
Clinical specificity =99.44% (95%CI*98.00% ~ 99.93%) Accuracy=99.49% (95%CI*98.18% ~ 99.94%)

Rubella IgG Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	30	2	32
	Negative	0	356	356
Total Results		30	358	388

Rubella IgG Study Summary Results: Clinical sensitivity >99.00% (95%CI*90.50% ~ 100.0%)
Clinical specificity=99.44% (95%CI*98.00% ~ 99.93%) Accuracy=99.48% (95%CI*98.15% ~ 99.94%)

CMV IgM Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	35	3	38
	Negative	1	327	328
Total Results		36	330	366

CMV IgM Study Summary Results: Clinical sensitivity =97.22% (95%CI*85.47% ~ 99.93%)
Clinical specificity =99.09% (95%CI*97.37% ~ 99.81%) Accuracy=98.91% (95%CI*97.23% ~ 99.70%)

CMV IgG Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	36	2	38
	Negative	0	328	328
Total Results		36	330	366

CMV IgG Study Summary Results: Clinical sensitivity >99.00% (95%CI*92.02% ~ 100.0%)
Clinical specificity=99.39% (95%CI*97.83% ~ 99.93%) Accuracy=99.45% (95%CI*98.04% ~ 99.94%)

HSV1 IgM Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	28	1	29
	Negative	2	348	350
Total Results		30	349	379

HSV1 IgM Study Summary Results: Clinical sensitivity =93.33% (95%CI*77.93% ~ 99.18%)
Clinical specificity =99.71% (95%CI*98.41% ~ 99.99%) Accuracy=99.21% (95%CI*97.70% ~ 99.84%)

HSV1 IgG Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	29	3	32
	Negative	0	346	346
Total Results		29	349	348

HSV1 IgG Study Summary Results: Clinical sensitivity >99.00% (95%CI*90.19% ~ 100.0%)
Clinical specificity=99.14% (95%CI*97.51% ~ 99.82%) Accuracy=99.21% (95%CI*97.70% ~ 99.84%)

HSV2 IgM Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	26	1	27
	Negative	1	321	322
Total Results		27	322	349

HSV2 IgM Study Summary Results: Clinical sensitivity =96.30% (81.03% ~ 99.91%)
Clinical specificity =99.69% (98.28% ~ 99.99%) Accuracy=99.43% (97.95% ~ 99.93%)

HSV2 IgG Study		PCR		
ToRCH IgG/IgM Rapid test	Results	Positive	Negative	Total Results
	Positive	28	2	30
	Negative	1	320	321
Total Results		29	322	351

HSV2 IgG Study Summary Results: Clinical sensitivity =96.55% (82.24% ~ 99.91%)
Clinical specificity=99.38% (97.77% ~ 99.92%) Accuracy=99.15% (97.52% ~ 99.82%)

Interference Substances
The following potential interfering substances have been tested using The kit and no interference was observed:

Substance	Tested Concentration
Antinuclear antibody (ANA)	100 IU/mL
Anti-mitochondrial antibody(AMA)	80 U/mL
Human albumin	110 mg/mL
Bilirubin	1 mg/mL
Hemoglobin	10 mg/mL
Cholesterol	0.2 mg/mL
Triglycerides	15 mg/mL

Cross Reaction
FRENOVO ToRCH IgG/IgM Rapid Test Kit was tested with specimens from patients diagnosed with HAV, HBV, HCV, HEV, HIV, RF, Syphilis, HAMA, Mononucleosis positive specimens. The results showed no cross reactivity.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

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INSTRUCTION APPROVAL AND REVISION DATE

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