CE IVD

FRENOVO

Rubella IgG/IgM Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Rubella IgG/IgM Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Rubella IgG/IgM Rapid Test is a lateral flow immunoassay for the semi-quantitative detection and differentiation of IgG and IgM antibodies to rubella virus in human serum, plasma or whole blood. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with rubella virus.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

An infection with rubella virus occurs most often during childhood. The infection usually leads to mild symptoms including maculopapular rash of head and trunk, fever, arthritis and lymphadenopathy. However, if a rubella virus infection occurs during pregnancy, a group of birth defects collectively known as congenital rubella syndrome (CRS) may develop, including congenital eye defects, deafness, congenital heart diseases and mental retardation1 . Clinical diagnosis of Rubella is unreliable and unspecific. Therefore, laboratory diagnosis is essential to confirm an acute infection. During an acute infection with rubella virus, anti-rubella virus IgM can be detected 3-6 days after onset of symptoms and generally decrease to undetectable levels within 12-14 weeks. Anti-rubella virus IgG can be detected within 2-3 weeks post infection and levels may rise during the acute phase of the disease to levels above 200 IU/mL. Protective immunity from an infection with rubella virus is indicated by an anti-rubella virus IgG level ≥ 10-15 IU/mL. However, the presence of anti-rubella virus IgG ≥10-15 IU/mL does not necessarily ensure protection from future infection with rubella virus. A patient without protective levels of anti-rubella virus IgG (< 10-15 IU/mL) is considered at risk of acquiring a rubella virus infection during pregnancy.

FRENOVO Rubella 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 Rubella 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 Rubella antibody IgG, the presence of a colored line in the test line (M) region indicates a positive result for Rubella 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: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
3. Droppers: 20 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 Rubella 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 inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

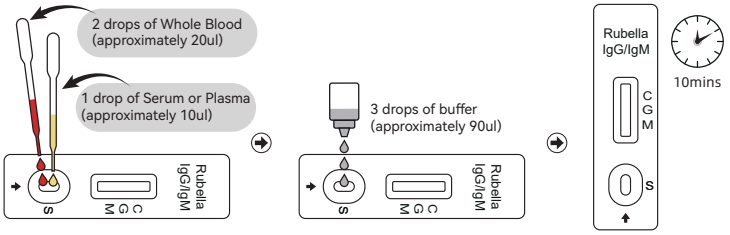
To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.

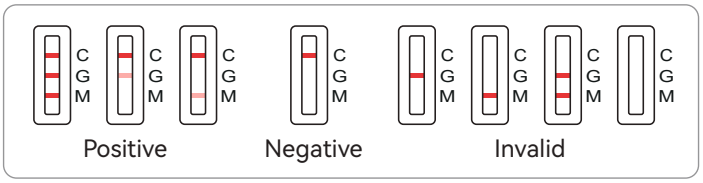
For Whole Blood Specimens

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 inside (approximately 90ul) 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 inside (approximately 90ul) 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 Rubella 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 Rubella specific-IgG and is probably indicative of secondary Rubella 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 Rubella specific-IgM antibodies and is indicative of primary Rubella infection.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of Rubella 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 Rubella IgG/IgM antibodies in serum, plasma or whole blood specimens only.
2. A negative test result cannot exclude a recent infection. A positive result may not indicate previous Rubella infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
3. A negative or non-reactive result can occur if the quantity of the anti-Rubella antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
4. Results from this test should not be used to diagnose or to exclude acute Rubella 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:

Rubella IgM Study		PCR		
Rubella 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		
Rubella 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%)

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	0.2mg/ml
Triglycerides	15 mg/mL

Cross Reaction

FRENOVO Rubella 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℃ 30℃	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	CE	CE mark

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INSTRUCTION APPROVAL AND REVISION DATE

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