Chlamydia Pneumoniae IgG/IgM Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Chlamydia Pneumoniae IgG/IgM in human serum, plasma or whole blood specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME

Chlamydia Pneumoniae IgG/IgM Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The Chlamydia pneumoniae IgG/IgM Combo Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG and IgM antibody to Chlamydia pneumoniae in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with L. interrogans. Any reactive specimen with the Chlamydia pneumoniae IgG/IgM Combo Rapid Test must be confirmed with alternative testing method(s).

INTRODUCTION

Chlamydia pneumoniae (C. pneumoniae) is a common species of bacteria and a major cause of pneumonia around the world. Approximately 50% of adults have evidence of past infection by age 20, and reinfection later in life is common. Many studies have suggested a direct association between C. pneumoniae infection and other inflammatory diseases such as atherosclerosis, acute exacerbations of COPD, and asthma.

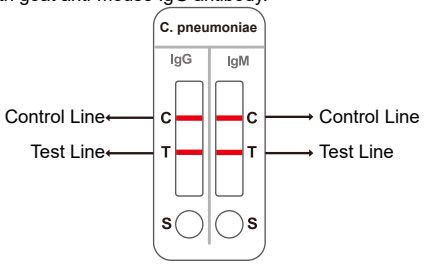
Diagnosis of C. pneumoniae infection is challenging due to the fastidious nature of the pathogen, the considerable seroprevalence, and the possibility of transient asymptomatic carriage. Established diagnostic laboratory methods include isolation of the organism in cell culture, serological assays and PCR. Microimmunofluorescence test (MIF), is the current “gold standard” for serological diagnosis, but the assay still lacks standardization and is technically challenging. Antibody immunoassays are the most common serology tests used and primary chlamydial infection is characterized by a predominant IgM response within 2 to 4 weeks and a delayed IgG and IgA response within 6 to 8 weeks. However, in reinfection, IgG and IgA levels rise quickly, often in 1-2 weeks whereas IgM levels may rarely be detected. For this reason, IgA antibodies have shown to be a reliable immunological marker of primary, chronic and recurrent infections especially when combined with the detection of IgM.

PRINCIPLE

Chlamydia pneumoniae IgG/IgM Rapid Test kit is based on the principle of a qualitative immunochromatographic assay for the determination of Chlamydia pneumoniae IgG/IgM antibody in the in human serum, plasma or whole blood.

StripA consists of: 1) a burgundy colored conjugate pad containing C. pneumoniae antigen conjugated with colloid gold (C. pneumoniae Antigen conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with mouse anti-human IgG antibody, and the C band is pre-coated with goat anti-mouse IgG antibody.

Strip B consists of : 1) a burgundy colored conjugate pad containing C. pneumoniae antigen conjugated with colloid gold (C. pneumoniae Antigen conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with mouse anti-human IgM antibody, and the C band is pre-coated with goat anti-mouse IgG antibody.



Strip A:When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette.C. pneumoniae IgG antibody if present in the specimen will bind to the C. pneumoniae Antigen conjugates. The immunocomplex is then captured on the membrane by the pre-coated Mouse anti-human IgG antibody, forming a burgundy colored T band, indicating a C. pneumoniae IgG positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

Strip B:When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette.C. pneumoniae IgM antibody if present in the specimen will bind to the C. pneumoniae Antigen conjugates. The immunocomplex is then captured on the membrane by the pre-coated Mouse anti-human IgM antibody, forming a burgundy colored T band, indicating a C. pneumoniae IgM positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 tests/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution	25tubes(300ul/ tube)	5tubes(300ul/ tube)	300ul/tube
Dropper	25 pcs	5 pcs	1 pcs
Lancet	25 pcs	5 pcs	1 pcs
Alcohol pad	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

Main ingredients of Sample Diluent Solution:

Neutral salt buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing use

PRECAUTIONS

- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

STORAGE AND STABILITY

- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination.
- Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

ASSAY PROCEDURE

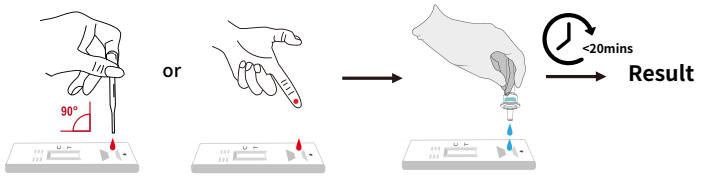
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Be sure to label the device with specimen’s ID number.

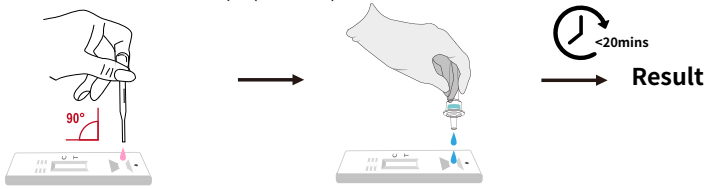
Step 4: **For whole blood test**

- Apply 1 drop of whole blood (about 30 μL) into the sample well.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



For serum or plasma test

- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (about 60).



Step 5: Set up timer.

Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don’t read results after 30 minutes

QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:

a. New operator uses the kit, prior to performing testing of specimens.

b.A new lot of test kit is used.

c.A new shipment of kits is used.

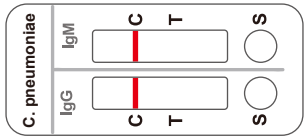
d.The temperature used during storage of the kit fall outside of 2~30°C.

e.The temperature of the test area falls outside of 15~30°C.

INTERPRETATION OF ASSAY RESULT

Negative Control

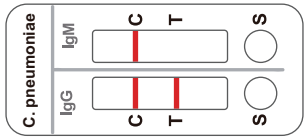
If only the C band is developed, the test indicates that no detectable C. pneumoniae IgG/IgM is present in the specimen. The result is non-reactive.



Positive Control

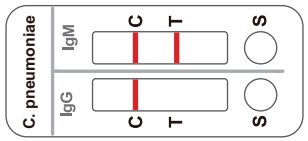
C. pneumoniae IgG positive

If only the C band is developed, the test indicates that no detectable C. pneumoniae IgG is present in the specimen. The result is non-reactive.



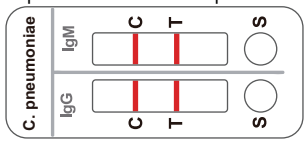
C. pneumoniae IgM positive

If both C and IgM lines are developed, the test indicates the presence of C. pneumonia IgM antibody in the specimen. The result is positive.



IgG and IgM antibody positive

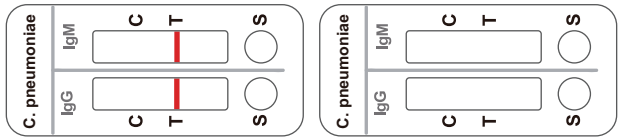
If both C, IgG and IgM lines are developed, the test indicates the presence of C. pneumonia IgG/IgM in the specimen. The result is positive.



INVALID:

If no C line is developed, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new test device.

Excess fecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).



The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

A total of 240 samples from susceptible subjects were tested by the C. pneumonia IgG/IgM Combo Rapid Test and by a commercial C. pneumonia IgM EIA kit. Comparison for all subjects is showed in the following table.

	Chlamydia pneumoniae IgG/IgM Rapid Test kit		
IgM EIA	Positive	Negative	Total
Positive	39	1	40
Negative	2	198	200
Total	41	199	240
Relative Sensitivity: 97.5.0%, Relative Specificity: 99.0%, Overall Agreement: 98.75%			

2. Clinical Performance For IgG Test

A total of 228 samples from susceptible subjects were tested by the C. pneumonia IgG/IgM Combo Rapid Test and by a commercial C. pneumonia IgG EIA kit. Comparison for all subjects is showed in the following table.

	Chlamydia pneumoniae IgG/IgM Rapid Test kit		
IgG EIA	Positive	Negative	Total
Positive	26	2	28
Negative	2	198	200
Total	28	200	228
Relative Sensitivity: 92.86% , Relative Specificity: 99.0%, Overall Agreement: 98.25%			

TEST LIMITATIONS

1.The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to pathogenic C. pneumonia in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

2.The Chlamydia pneumoniae IgG/IgM Combo Rapid Test is limited to the qualitative detection of antibodies to C. pneumoniain human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with antibody titer in the specimen.

3.A negative result for an individual subject indicates absence of detectable C. pneumonia antibodies. However, a negative test result does not preclude the possibility of exposure to C. pneumonia.

4.A negative result can occur if the quantity of C. pneumonia 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.

5.Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

6.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings..

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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