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Rickettsia IgG/IgM Combo Test

Cat #: R13-561

For In Vitro Diagnostic Use Only

A Rapid qualitative Immunochromatographic test for the simultaneous detection of IgG and IgM Antibodies to Rickettsia in human Whole Blood, Serum or plasma

INTRODUCTION

Immunospec Rickettsia Test is a rapid immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to Rickettsia in human whole blood, serum or plasma. The assay is used as a screening test for Rickettsia infection and as an aid for differential diagnosis of primary and secondary infections in conjunction with other criteria.

SUMMARY

Members of the genera Rickettsia and Orientia are morphologically and biochemically similarto other gram-negative bacteria, They are, however, fastidious bacterial organisms that are obligate intracellular parasites. Although rickettsial species are arthropod-associsated bacteria, they are also frequently capable of infecting vertebrates, including human, usually as accidental hosts. Rickettsiae are transmitted to humans by infected arthopodbites or feces. The main symptoms of infection consist of fever and headache. Cutaneous eruption, which is sometimes associated with inoculation eschar, is reported in most cases. The pathogenesis of these diseases is vasculitis caused by the proliferation of organisms in the endothelial lining of small arteries, veins, and capillaries.

Immunspec Rickettsia Test is *a* new generation rapid Immuno-chromatographic test using recombinant bacterial antigens to detect specific antibody response.

TEST PRINCIPLE

Immunspec Rickettsia Test utilizes the principle of Immunochromatography. Anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgG line in the test window is closer to the sample well and followed by IgM line. As the test sample flows through the membrane assembly within the test device, the colored Rickettsia specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM or IgG) of Rickettsia, if present in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-human IgM and/or human IgG binding proteins coated on the membrane leading to formation of a colored band, which confirms a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-Rickettsia virus antibodies in the specimen.

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:
1. Rickettsia Test card in foil pouch
2. Sample buffer
3. Sample tube
4. Product insert

MATERIALS NOT PROVIDED

1. Sepcimen collection container
2. Timer

STORAGE AND STABILITY

1. The sealed pouches in the test kit may be stored between 2-30ºC for the duration of the shelf life as indicated on the pouch.
2. The sample buffer should he stored at 2-8ºC

PRECAUTIONS

1. This kit is for ***IN VITRO*** diagnostic use only.
2. This kit is for ***PROFESSIONAL*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is complete, dispose specimens after autoclaving them at 121º C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and no smoking or eating while performing assays.
9. Wear gloves during the whole procedure.

SPECIMEN COLLECTION AND PREPARATION

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. Fresh serum / plasma is preferable. Serum / plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods.
3. The test works best on fresh whole blood samples. If testing cannot be done immediately, Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate should be stored at 2-8ºC up to 3 days. Blood samples should not be frozen.
4. Repeated freezing and thawing of the specimen should be avoided.
5. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
7. Do not heat inactivate the sample.
8. Shipment of samples should comply with local regulations for transport of etiologic agents.

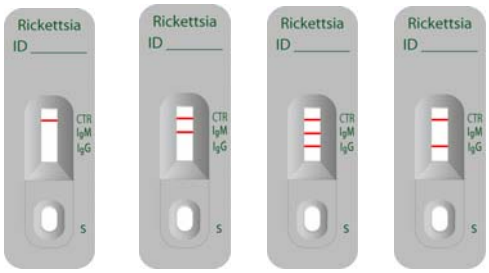
PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the Card. Once opened, the test card must be used immediately.
3. Label the test card with patients identity.
4. Add 4 drops of sample buffer to the enclosed sample tube.
5. Apply 5 µL of serum, plasma or 10 µL of whole blood to the sample tube.
6. Put the cap of the sample tube back and gently tap or shake the tube to mix the sample with sample buffer well.
7. Hold the tube vertically with the tip towarding to the sample well marked as "**S**", add 3 drops.

8. At the end of 15 minutes read the results. A strong positive sample may show result earlier.

INTERPRETATION OF RESULTS

1. *Negative*
   Only control line appears.
2. *IgM Positive*
   Both control line and the second test line (the higher test line) appear. It indicates the possibility of primary infection.
3. *IgM and IgG Positive*
   Control line and both test lines appear. It indicate the possibility of acute secondary infection.
4. *IgG Positive*
   Both control line and the second test line (the lower test line which is closer to the sample well) appear. It indicates the possibility the secondary infection or past infection.
5. *Invalid Result*
   If after 15 minutes no line is visible within the test or control window, the result is invalid. The test should be repeated with a new test card.



Negative IgM Pos. IgG/IgM Pos. IgG Pos.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

LIMITATIONS

1. The test is for qualitative detection of anti-Rickettsia antibody in human serum, plasma or blood sample and dose not indicate the quantity of the antibodies.
2. The test is for *in vitro* diagnostic use only.
3. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.

PERFORMANCE CHARACETERISTICS

1. **Accuracy**

Thirty six (36) confirmed rickettsia samples and fifty (50) normal samples were tested. Immunospec Rickettsia Test showed 100% accuracy.

		Confirmed Clinical Results		
Immunospec Rickettsia Test		Positive	Negative	Total
	Positive	36	0	36
	Negative	0	50	50
Total		36	50	86

Sensitivity = 36/36 = 100%

Specificity = 50/50 = 100%

2**. Interference**

These compounds do not affect the test sensitivity and specificity at the indicated concentrations.

bilirubin	10 mg/dL
hemoglobin	20mg/dL
triglycerides	300 mg/dL

REFERENCES

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3. Yeau-Ching Wang, et al. Development of a recombinant protein-based ELISA and its applications in field surveillance of rodent mice for presence of IgG against orientia tsutsugamushi, Clin. And Diag. Lab. Immunology, 10:451-458, 2003

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