CDIA™ Leptospira IgG/IgM Colloidal Gold Test Kit (serum/plasma/whole blood)

Cat. No.: DTSJZ020

Pkg. Size: 25T

Intended Use

The Leptospira IgG/IgM Colloidal Gold Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG and IgM antibodies to Leptospira interrogans (L. interrogans) 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 Leptospira IgG/IgM Combo Rapid Test must be confirmed with alternative testing method(s).

General Description

Leptospirosis occurs worldwide and is a common mild to severe health problem for humans and animals, particularly in areas with hot and humid climates. The natural reservoirs for leptospirosis are rodents as well as a large variety of domesticated mammals. Human infection is caused by L. interrogans, the pathogenic member of the genus of Leptospira1,2. The infection is spread via urine from the host animal.

After infection, leptospires are present in the blood until they are cleared approximately 4 to 7 days after the onset of the disease following the production of anti-L. interrogans antibodies, initially of the IgM class. Culture of the blood, urine and cerebrospinal fluid is an effective means of confirming the diagnosis during the 1st and 2nd weeks after exposure. Serological detection of anti-L. interrogans antibodies is also a common diagnostic method. CDIATM Leptospira IgG/IgM Colloidal Gold Test is a simple serological test that utilizes antigens from L. interrogans and detects IgG and IgM antibodies to these microorganisms simultaneously. The test can be performed by untrained or minimally skilled personnel without cumbersome laboratory equipment, and the result is available within 15 minutes.

Principle of the Test

The Leptospira IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant L. interrogans antigens conjugated with colloidal gold (Leptospira conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test lines (M and G lines) and a control line (C line). The M line is pre-coated with monoclonal anti-human IgM for the detection of anti-L. interrogans IgM, G line is pre-coated with reagents for the detection of anti-L. interrogans IgG, and the C line is pre-coated with goat anti rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. IgM anti-L. interrogans, if present in the specimen, will bind to the Leptospira

45-1 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 Fax: 1-631-938-8221
E-mail: info@creative-diagnostics.com
www.cd-diatest.com

conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody forming a burgundy colored M line, indicating a L. interrogans IgM positive test result. IgG anti-L. interrogans, if present in the specimen, will bind to the Leptospira conjugates. The immunocomplex is then captured on the membrane by the pre-coated reagents forming a burgundy colored G line, indicating a L. interrogans IgG positive test result.

Absence of any test lines (M and G) suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugates regardless of color development on any of the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

Reagents and Materials Provided

1. Cassette, 25 T
2. Kit insert

Sample Preparation

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.

2. Separate the plasma by centrifugation.

3. Carefully withdraw the plasma into new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.

2. Allow the blood to clot.

3. Separate the serum by centrifugation.

4. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately, up to 5 days. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use hemolized blood for

45-1 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 Fax: 1-631-938-8221
E-mail: info@creative-diagnostics.com
www.cd-diatest.com

testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

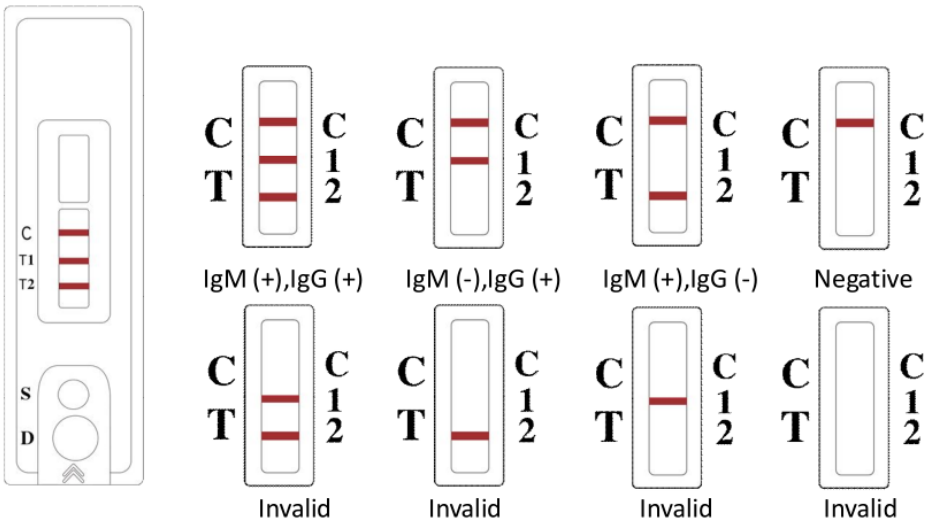
Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C-30°C prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10°C-50°C)

1. Take off the outer packing, put the cassette onto the desk with the sample window up.
2. Drop 1 drops of serum or plasma (30μl-45μl) or 1 drop of whole blood (40-50μl) vertically into the sample hole of cassette well, making sure that there are no air bubbles. Add about 1 drops of (40μl-50μl) sample buffer into the sample hole of cassette immediately.
3. Observe the test results immediately within 15 minutes.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

Result Interpretation



POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T1 test region (T1), indicating the presence of IgG anti-L. interrogans in the specimen.

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the T2 test region (T2), indicating the presence of IgM anti-L. interrogans in the specimen.

POSITIVE: Three distinct red lines appear in the control region (C), the T1 test region (T1) and the T2 test region (T2), indicating the presence of both IgG and IgM anti-L. interrogans in the specimen .

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T1 and T2).

45-1 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 Fax: 1-631-938-8221
E-mail: info@creative-diagnostics.com
www.cd-diatest.com

INVALID: No red bands appear or control line fails to appear, indicating that the operator error or reagent failure.

Result Interpretation

1. Clinical Performance For IgM Test

A total of 210 samples from susceptible subjects were tested by the Leptospira IgG/IgM Rapid Test and by a commercial Leptospira IgM EIA kit. Comparison of the results for all subjects is shown in the following table.

Leptospira IgG/IgM Rapid Test			
IgM EIA	Positive	Negative	Total
Positive	9	1	10
Negative	2	198	200
Total	11	199	210

Relative Sensitivity: 90.0%, Relative Specificity: 99.0%, Overall Agreement: 98.6%

2. Clinical Performance For IgG Test

A total of 206 samples from susceptible subjects were tested by the Leptospira IgG/IgM Rapid Test and by a commercial Leptospira IgG EIA kit. Comparison of the results for all subjects is shown in the following table.

Leptospira IgG/IgM Rapid Test			
IgG EIA	Positive	Negative	Total
Positive	6	0	6
Negative	2	198	200
Total	8	198	206

Relative Sensitivity: 100%, Relative Specificity: 99.0%, Overall Agreement: 99.0%

Storage

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Limitation

1. The Assay Procedure and the Interpretation Assay Result sections must be followed closely when testing for the

45-1 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 Fax: 1-631-938-8221
E-mail: info@creative-diagnostics.com
www.cd-diatest.com

presence of antibodies to pathogenic L. interrogans in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

2. The Leptospira IgG/IgM Combo Rapid Test is limited to the qualitative detection of antibodies to L. interrogans in human serum, plasma or whole blood. The intensity of the test line does not have a linear correlation with antibody titer in the specimen.

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

4. A negative result can occur if the quantity of L. interrogans 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 titers 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.

For in Vitro Diagnostic Use

Precaution

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

2. Do not open the sealed pouch, unless ready to conduct the assay.

3. Do not use expired devices.

4. Bring all reagents to room temperature (15°C-30°C) before use.

5. Do not use the components in any other type of test kit as a substitute for the components in this kit.

6. Do not use hemolized blood specimen for testing.

7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.

8. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.

9. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.

10. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.

11. Handle the Negative and Positive Control in the same manner as patient specimens.

12. The testing results should be read within 10 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 10 minutes may give erroneous results.

13. Do not perform the test in a room with strong air flow, ie. an electric fan

45-1 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 Fax: 1-631-938-8221
E-mail: info@creative-diagnostics.com
www.cd-diatest.com