Leptospira IgG/IgM

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INTENDED USE:
Rapid differential detection kit for IgG and IgM antibody against Leptospira interrogans

EXPLANATION OF THE TEST
Leptospria IgG/IgM is a chromatographic immunoassay kit for rapid and differential detection kit of immunoglobulin G (IgG) and immunoglobulin M (IgM) against Leptospira interrogans in human serum or plasma. This test is intended for professional use as an aid in the clinical laboratory diagnosis of patients with clinical symptoms consistent with leptospirosis. This test provides only a preliminary test result. Therefore, other serological test like MAT reference test, ELISA, PHA must be used in order to obtain a confirmation of Leptospira interrogans infection.
L.interrogans-specific antigen complexed with gold conjugate is placed in the conjugate pad and anti-human IgG and anti-human IgM are coated on the membrane. When antibody-positive specimen is loaded into sample injection point, the antibodies are captured the immobilized anti-human antibodies. And then, the antibodies are reacted with L.interrogans-specific antigen-gold complex to make a visible band in the test line regions. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line.

MATERIALS PROVIDED
Leptospira IgG/IgM kit contains the following components:
1. Test devices individually foil-pouched with a desiccant
2. Assay Buffer

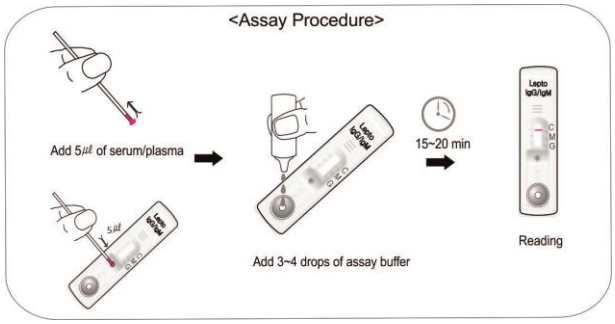
PRECAUTIONS
1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date and do not freeze the kit.
3. For *in-vitro* diagnostic use only. Do not re-use the test device.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose gloves, swabs, test tubes, and the used strips properly after test, in accordance with GLP.
6. Do not eat or smoke while handing specimens.
7. Decontaminate and dispose of all specimens and reaction waste should be done in a biohazard container.

SPECIMEN COLLECTION AND STORAGE
1. Specimen to be tested should be obtained and handled by standard methods for their collections.
A. Serum: allow the blood to clot, then centrifuge to separate the serum.
B. Plasma: collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
2. All specimens should be tested as soon as they are prepared. If necessary, they may be stored at 2-8 ℃ for up to 24 hours or at -20℃ for longer periods.
3. Precautions
A. Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
B. Use separately disposable capillary tubes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

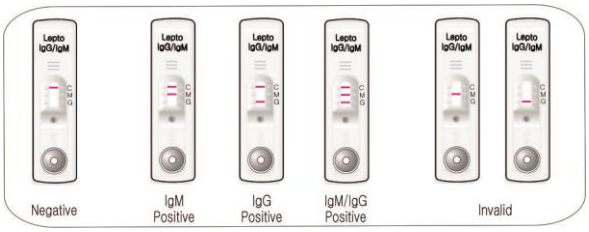
TEST PROCEDURE
1. Place all specimens, test devices, and Assay buffer and allow them to room temperature prior to testing (15~30min).
2. Using a sample dropper, add 5$\mu\ell$ of serum/plasma into the sample well (S).
3. Add 3~4 drops (approx. 100$\mu\ell$) of assay buffer into the buffer well (B) in the device. And then, after 15~20 minutes, interpret the test results.

* Please do not read the results after 30 minutes of this testing.

INTERPRETATION OF THE RESULTS



1. Negative: ONLY one band in the control line (C). No L.interrogans specific IgG and IgM were detected.
2. IgM Positive: Two bands are appeared in the IgM line (M) and control line (C). This is positive for IgM antibodies to L.interrogans and indicative of an acute L.interrogans infection.
3. IgG Positive: Two bands are appeared in the IgG line (G) and control line (C). This is positive for IgG antibodies and indicative of a secondary or previous L.interrogans infection.
4. IgG and IgM Positive: Three bands are appeared in the IgG line (G), IgM line (M) and control line (C). This is positive for both IgG and IgM antibodies to L.interrogans.
5. Invalid: If at ~10 minutes, the red color band does not appear in the control line (C), even if any shade of a pink-to-red test line (T) appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test device.



STORAGE & EXPIRATION

1. Leptospira IgG/IgM kit should be stored between 4 to 30℃.
2. Expiration date of this kit is 24 months after its manufacture date.

LIMITATIONS OF THE TEST

Leptospira IgG/IgM is designed for primary screening test of L.interrogans infections. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

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