SENSIT LEPTOSPIRA IgM RAPID TEST

Cat No.: S002-01

In vitro Diagnostics

INTENDED USE

Sensit Leptospira IgM antibody Rapid Test is a lateral flow immunoassay for the qualitative detection of IgM antibody against Leptospira interrogansin whole blood, plasma or serum. This test is intended to be used as a screening test and as an aid in the diagnosis of Leptospira infection. Any reactive specimen with the ubio Sensit Leptospira antibody Rapid Test must be confirmed with alternative testing methods.

SUMMARY & TEST DESCRIPTION

Leptospirosis is a bacterial disease that affects both humans and animals. Humans become infected through direct contact with the urine of infected animals or with a urine-contaminated environment. The bacteria enter the body through cuts or abrasions on the skin, or through the mucous membranes of the mouth, nose and eyes. Without treatment, Leptospirosis can lead to kidney damage, meningitis (inflammation of the membrane around the brain and spinal cord), liver failure, respiratory distress, and even death.

Sensit Leptospira IgM antibody Rapid Test is for the qualitative determination of IgM antibodies developed during Leptospirosis infection.

TEST PRINCIPLE

The Sensit Leptospira IgM Antibody Rapid Test is a lateral flow chromatographic immunoassay. The test strip consists of 1) a pink coloured conjugate pad containing Anti-Human IgM conjugated with colloid gold, 2) a nitrocellulose membrane strip pre-coated with recombinant Leptospira Antigen on test line and Goat Anti-Mouse on Control line. Test specimen, with adequate amount of buffer, migrates along the conjugate pad and further across the coated membrane by capillary action. Leptospira IgM antibodies present in the sample, complex with the Anti-Human IgM present in the conjugate pad and gets captured onto the coated Leptospira antigen. Thus, giving a coloured test band, indicating a positive test result. If the respective antibody is not present in the sample, no reaction occurs and no test line is formed. The sample then migrates further along the strip until it reaches the control band, where excess Anti-Human IgM-CGC gets bound and produces a second visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended

REAGENTS & MATERIALS PROVIDED

1. Each Kit contains 30 test devices, each sealed in a foil pouch containing following items:
   a. One test strip
   b. Desiccant
2. Assay Diluent - In dropper bottle
3. Instruction Leaflet

PRECAUTIONS & WARNING

1. Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
2. Do not use with specimen containing precipitates
3. Use within 10 minutes after opening pouch.
4. Do not reuse test kit.
5. Use only the buffer supplied along with the kit.
6. Do not mix components from different kits.
7. Use only for in-vitro diagnostic purpose.
8. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.

SAMPLE PREPARATION & STORAGE

- Plasma: Collect the whole blood using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Centrifuge the blood to get plasma specimen as supernatant.
- Serum: Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5days, freezing is recommended. Store at -20^{0}C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

STORAGE & STABILITY

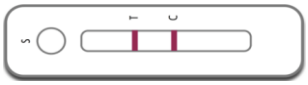
Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the foil pouch is brought to room temperature before opening.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10µl of whole blood/Serum to the Sample well "S"
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
4. Wait for 10 minutes and interpret results. All results where control band does not appear are considered invalid.

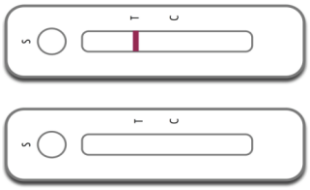
INTERPRETATION OF TEST RESULT

Positive: Color bands at position C and T. IgM antibody against Leptospira antigen is present in the sample



Negative: Color band at position C. IgM antibody against Leptospira antigen is not present in the sample

Invalid: Color band at C does not appear



Reference:

1. Lateral-flow assay for rapid serodiagnosis of human leptospirosis.
Smits HL, Eapen CK, Sugathan S, Kuriakose M, Gasem MH, Yersin C, Sasaki D, Pujianto B, Vestering M, Abdoel TH, Gussenhoven GC. Clin Diagn Lab Immunol. 2001 Jan;8(1):166-9.

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