ACCUCARE
Leptospira IgM

A rapid and sensitive test for the qualitative detection of IgM antibodies to the Leptospira organisms in human serum, plasma, or whole blood.

INTENDED USE

For Accucare Leptospira IgM Rapid Test is a qualitative test for detection of IgM antibodies to Leptospira organism in human serum plasma or whole blood. The test provides detection of anti-Leptospira-IgM antibodies and can be used for the presumptive diagnosis of a primary Leptospira infection. This test is for In-Vitro Diagnostics use only.

SUMMARY

The clinical manifestations of leptospirosis range from a mild catarrh like illness to icteric disease with servere liver and kidney involvement. Natural reservoirs for leptospirosis include rodent as wll as a large variefy of domesticated mammals. The organisms occupy the lumen of nephritic tubules in their natural host and are shed in to the urince. Human infection derives from direct exposure to infected animals for e.g. (veteringarians, abattoir workers, of daity exposure to environment contaminated by animal carriers (e.g. agricultural workers). Bathing or swimming in water sources about which live stock have been pastured has been demonstrated to be a potential infection hazard. The organisms enter the host through skin abrasions, mucosal surfaces or the eye. The incubation. period can range from 3 to 30 days but is usually found to be 10 to 12 days . Antibodies can become detectable by the 6th to 10th day of diseace and generally reach peak levels within 3 to 4 weeks. Antibody levels then gradually recede but may remain detectable for years.

Epidemiologic factors, clinical findings, exposures in endemic regions, and other laboratory results should be considered in diagnosing acute disease. Acute disease diagnosis will also include a positive laboratory confirmation in many cases. The test is designed to measure acute infections with leptospira. Confirmation of a positive sample by additional methods should be followed.

PRINCIPLE

The Accucare Leptospira IgM Rapid Test is a qualitative test for the detection of IgM antibodies to Leptospira organism in human serum, plasma or whole blood. The test provides detection of anti-Leptospira-IgM antibodies and can be used for the presumptive diagnosis of primary Leptospira infection. Serum, plasma or whole blood samples may be used with this test. First a specimen is dispensed with sample buffer , the IgM anitibodies in the specimen sample which in turn will bind with Leptospira antigen coated on the membrane. The Leptospira antigen on the membrance will bind the IgM antibody complex at the test line causing pale or dark pink line to form at the test line region of the test membrane The intensity of the line will vary depending upon the amount of antibody present in the sample. The appearance of pink line in the test region should be considered as positive for IgM.

REAGENTS

The test device contains recombinant Leptospira antigens coated on the membrane and ati-Human IgM coated particies.

PRECAUTION

- For Professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimen or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimen (s) are being tested.
- Humidity and temperature can adversely affect results.
- The test should remain in the sealed pouch until use.
- Optional assay performance requires strict adherence to the assay procedure described in this instruction sheet and any deviations from procedure may lead to aberrant results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated -(4°-30 C). the test device is stable through the expiration date printed on the sealed pouch until use. DO NOT FREEZE.
Do not use deyond the expiration date.

MATERIALS

Materials provided:

- Test device
- Package Insert
- Assay Buffer
- Sample Dropper

Material Required but not provided:

- Timer
- Specimen Dropper

Specimen collection & preparation

- The Accucare Leptospira Test Device (serum/plasma/whole blood) can be performed using serum, plasma or whole blood.
- Separate the serum or plasma as soon as possible to avoid hemolysis, Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimen may be stored at 2-8° C for up to 3 days. For long-term storage, specimen should be kept below-20° C.
  Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

DIRECTIONS FOR USE:

Allow test device serum plasma or whole blood specimen, and/or controls to equilibrate to room temperature (15-30° C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device form the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Add 10 ul of serum, plasma or 20 ul of whole blood specimen well “A” well of the device.
3. Add 1 drop (40 ul) of buffer to the specimen to the (A) of the test device immediately after the specimen is added, and then start the timer.
4. Wait for the red line (S) to appear. The test result should be read at 15 minutes. It is important that the background is clear before the result is read.

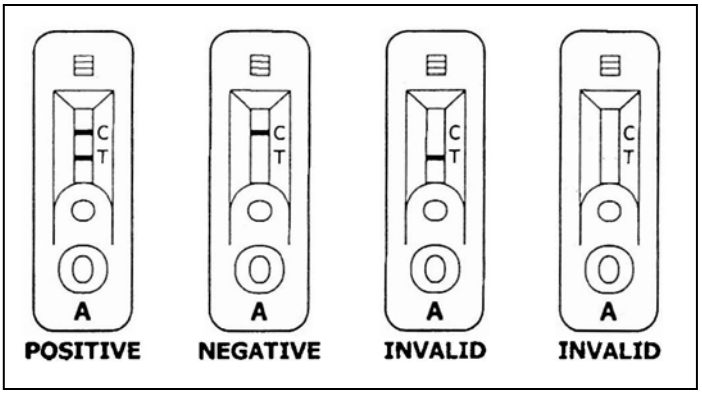
INTERPRETATION OF THE RESULTS

IgM POSITIIVE: Two distinct red lines appear. The control line (C) and IgM (T) line are visible on the test cassette. The test is positive for IgM antibodies. This is indicative of a primary infection.

NEGATIVE: One distinct red line appear. The control line (C) is the only line visible on the test cassette. No IgM antibodies were detected. The result does not exclude Leprospira infection. A new sample should be drawn from the patient in 3-5 days and then should be retested.

INVALID: Control line fails to appear. The test result are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the IgM (T) region of the cassette. Repeat the test using a new cassette

Note: The intensity of the red color in the test line regions. (T) will vary depending on the concentration of IgM present in the specimen. However, neither the quantitative value nor the rate of 1increase in IgM can be determined by this qualitative test.



QUALITY CONTROL

A procedural control is included in the test. A Red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and control procedural technique. A clear background is also required.

BIBLIOGRAPHY

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