COD: 340 Leishmania Test
25 TEST

distribuito da:

LEISHMANIA Test

A rapid immunochromatographic strip assay for the qualitative detection of antibodies to Visceral Leishmania in serum

Summary and Explanation

Leishmania is a severe disease with high mortality, endemic in 88 countries including 17 developed nations . A serious problem in much of the world including Brazil, China, East Africa, India and areas of the Middle East.

Leishmaniasis is also endemic in the Mediterranean region including southern France, Italy, Greece, Spain, Portugal and Northern Africa. In areas where leishmaniasis is endemic, recent migration patterns of people, vectors (sandfly) and reservoirs (dogs) has led to the urbanization of VL . In Southern Europe VL has become the leading opportunistic infection in AIDS patients.

VL is caused by members of the *Leishmania donovani* complex and canines have been identified as the major reservoir for transmission . Serodiagnosis has been widely utilized to establish infection because antileishmanial antibody titers are high during acute disease.

The preferred method of diagnosis in a laboratory situation is by ELISA, although fluorescent antibody (IFAT) or direct agglutination tests (DAT), both utilizing whole parasites, are still widely used. These tests are highly cross-reactive with trypanosomes and mycobacteria. In addition, the whole parasite preparations used are unstable and variable in quality.

This rapid assay for the qualitative determination of antibodies to a recombinant antigen (K39) specific for visceral leishmaniasis caused by parasite members of the *L. donovani* complex. The test does not cross react with other parasitic diseases, e.g. Chagas, Malaria.

Principle

The Cypress' Visceral Leishmania (kala-azar) test is a qualitative, membrane based immunoassay for the detection of antibodies to Visceral Leishmania (VL) in serum.

The membrane is precoated with a novel recombinant VL antigen (k39) on the test line region and chicken anti-protein A on the control line region.

During testing, the serum sample reacts with the dye conjugate (protein A-colloidal gold conjugate) which has been pre-coated in the test device.

The mixture then migrates upward on the membrane chromatographically by capillary action to react with recombinant VL antigen on the membrane and generate a red line.

Presence of this red line indicates a positive result, while its absence indicates a negative result. Regardless of the presence of antibody to VL, as the mixture continues to migrate across the membrane to the immobilized chicken anti-protein A region, a red line at the control line region will always appear.

The presence of this red line serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

Precautions

For professional *in-vitro* diagnostic use only.

Do not use after expiration date.

Storage

This test is designed to be stored at room temperature (15° C-25° C) or refrigeration (2° C - 8° C) in a sealed pouch or vial for the duration of its shelf-life.

Exposure to temperatures over 30° C can impact the performance of the test and should be minimized.

The strips should not be frozen and must be protected from exposure to humidity. The test should be used within 1 hour after removal from the pouch or vial.

Specimen Collection

Human serum may be tested with this test strip. Whole blood or dilutions of serum cannot be tested directly.

Remove the serum from the clot of red cells as soon as possible to avoid hemolysis.

Test should be performed as soon as possible after sample collection. Do not leave samples at room temperature for prolonged periods. Specimen can be refrigerated at 2-8° C up to 3 days. Otherwise specimens should be stored below -20° C.

Bring specimens to room temperature prior to testing. The frozen specimens must be completely thawed prior to testing. Specimens should not be repeatedly frozen and thawed.

Procedure

1. Allow the specimens and test strips to reach room temperature prior to testing.
2. Remove the test strip from the foil pouch or vial.
3. Add 20-30 m l of specimen to the test strip in the area beneath the arrow.
4. Place the test strip into a test tube or well of a 96 well tissue culture plate so that the end of the strip is facing downward as indicated by the arrows on the strip.

   Add 150 m l of the buffer solution provided with this test kit or two-three drops.
5. Place the test strip into a test tube or well of a 96 well tissue culture plate so that the end of the strip is facing downward as indicated by the arrows on the strip.
6. Add 150 m l of the buffer solution provided with this test kit.

Read the results in 10 minutes. It is significant that the background is clear before reading the test, especially when samples have low titer of anti-leishmania antibody, and only a weak band appears in the test region (T).

Do NOT interpret results after 10 minutes.

Note: Do not test this product with the chase buffer solution alone. 20-30 m l of human serum must be added first.

Result Interpretation

A Positive Result

The test is positive when a control line and test line appear in the test area as shown in Figure 1. A faint line is considered a positive result.

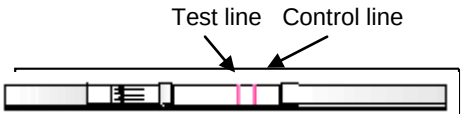

Figure 1

Test area, do not touch

A Negative Result : Only a single control line appears. A test line does not appear.

An Invalid Result : No lines appear. Retest with a new test strip for VL and fresh sample.

Note: The pink color in the test region will vary depending on the concentration of anti-Leishmania antibodies present. However, neither the quantitative value nor the rate of increase in antibodies can be determined by this qualitative test.

Performance characteristics

The Cypress' test for Visceral Leishmaniasis was clinically tested using sera from 175 patients with parasitologically proved diagnosis for Visceral Leishmaniasis. All 175 (100%) tested positive. Forty endemic healthy asymptomatic controls (first degree relatives living along with patients in the endemic area) were also tested. Of these, 38 (95%) were negative and two (5%) were positive for the antibodies.

Limitations

This test will only indicate the presence of antibodies to Visceral Leishmania in the specimen and should not be used as the sole criteria for the diagnosis of Leishmania. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

Persons with advanced HIV infection or other immunocompromised diseases frequently have low or undetectable anti-leishmanial antibodies .

If the result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result does not preclude the possibility of Leishmania.

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