IVD

Asan Easy Test® Leishmania Ab

ASAN

Diagnostic kit for the qualitative detection of Leishmania antibodies in human serum, plasma or whole blood

Immunochromatography

EXPLANATION OF THE TEST

The Asan Easy Test Leishmania Ab is a lateral flow immunoassay for the simultaneous detection to the subspecies of the Leishmania donovani (L. donovani), the Visceral leishmaniasis causative protozoans, in serum, plasma or whole blood. Leishmaniasis is caused by Leishmania infantum (Kinetoplastida:Trypanosomatidae), a protozoan characterized by the presence of an evident mitochondrial organelle, called kinetoplast. Flagelled forms of parasite, known as promastigotes, multiply in the gut of the insect vectors, the female of phlebotomus (Diptera: Psychodidae), that intradermically inoculates them in the host during the blood-feeding. Macrophages in the connective tissue phagocytize promastigotes, which become round-shaped and unflagelled and are named amastigotes. Amastigotes replicate in macrophages, destroying them and infecting progressively more and more phagocytes. Tests used in clinic are included ELISA, fluorescent antibody or direct agglutination tests 4-5. Recently, utilization of L. donovani specific protein in the test has improved the sensitivity and specificity dramatically6-7. Asan Easy Test Leishmania Ab is a recombinant protein based serological test, which detects antibodies to the L. Donovani simultaneously. The test provides a reliable result within 10~15 minutes without any instruments.

MATERIALS PROVIDED

Asan Easy Test® Leishmania Ab contains following items to perform the assay.

1. Test device individually foil-pouched with a desiccant
2. Assay solution
3. Instruction for use

SPECIMEN COLLECTION AND STORAGE

1. Specimen collection

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 (containg 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.

Whole Blood

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

2) Whole blood specimens should be stored in refrigeration (2~8°C) if not tested immediately.

3) The specimens must be tested within 24 hours of collection.

2. Specimen storage

Test specimens as soon as possible after collecting. Store specimens at 2~8°C, if not tested immediately. Store specimens at 2~8°C 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.

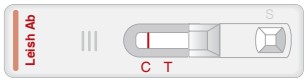
TEST PROCEDURE

1. All materials should be equilibrated to room temperature before performing the test.
2. Remove the test device from the pouch and place it on a flat surface.
3. Be sure to label the device with specimen's ID number.
4. Load 10μL of serum/plasma or 20μL of whole blood into the sample well. Then add 3drops (about 100-120 μL) of assay solution in a bottle.
5. Interpret the test results within 15minutes. Do not read result after 15minutes.

INTERPRETATION OF THE TEST

A. NEGATIVE RESULTS:

The presence of only one red color band("C"band) within the result window indicates a negative result.



B. POSITIVE RESULTS:

The presence of two color bands ("T"band and "C"band) within the result window regardless of which band appears first indicate a positive result for anti-L.donovani in specimen.

C. INVALID RESULTS:

If no band is visible within the window, the result is considered invalid. Some causes of invalid results are not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

STORAGE & EXPIRATION

1. Asan Easy Test Leishmania Ab should be stored at 1 ~ 30℃ (33.8 ~86 °F).
2. Expiration date of this kit is 24 months after its manufactuere date.

LIMITATIONS OF THE TEST

Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.

ASAN
ISO13485:2003

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