One-step Canine Heartworm antigen Test

Anigen Rapid

Canine Heartworm Antigen Test Kit

Principles

The Anigen Rapid Canine Heartworm Antigen Test Kit is a chromatographic immunoassay for the qualitative detection of Canine *Dirofilaria immitis* antigen in canine serum, plasma, or whole blood.

The Anigen Rapid Canine Heartworm Antigen Test Kit has a letter of "T" and "C" as test line and control line on the surface of the device. Both the test line and the control line in the result window are not visible before applying any samples. The control line is used for procedural control. The Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple color at the test line will be visible in the result window if there are heartworm antigens in the specimen.

The specially selected Canine *Dirofilaria immitis* antibodies are used in the test band as both capture and detector materials. These enable the Anigen Rapid Canine Heartworm Antigen Test Kit to identify Canine *Dirofilaria immitis* antigen in canine serum, plasma, or whole blood.

Materials provided

Materials	10 Tests/Kit	100 Tests/Kit
Anigen Rapid Canine Heartworm Antigen Test Device	10	100
Disposable droppers for specimen	10	100
Assay diluent bottle (Diluent contains sodium azide as a preservative)	1 (3ml)	4 (5ml)
Instructions for use	1	1

Precautions

1) For veterinary diagnostic use only.
2) For best results, strict adherence to these instructions is required.
3) All specimens should be handled as being potentially infectious.
4) Do not open or remove test devices from their individually sealed pouches until immediately before their use.
5) Do not use the test device if the pouch is damaged or the seal is broken.
6) Do not reuse test device.
7) All reagents must be at room temperature (15-30°C) before running the assay.
8) Do not use reagents beyond the stated expiration date marked on the label.
9) The components in this kit have been quality control tested as standard batch unit. Do not mix components from different lot numbers.
10) The assay diluent contains sodium azide, a hazardous chemical. The kit should be disposed of according to local regulations for hazardous materials and *in vitro* diagnostics.

Storage and Stability

The kit can be stored at room temperature or refrigerated (2-30°C). The test kit is stable through the expiration date marked on the package label. **DO NOT FREEZE.** Do not store the test kit in direct sunlight.

Specimen Collection and Preparation

1) The test can be performed with serum, plasma, or whole blood (with anticoagulant such as EDTA or heparin).
2) If specimens are not immediately tested, they should be refrigerated at 2-8°C. For storage more than 48 hours, freeze the specimen at -10°C or below.

*Note: Blood samples should not be frozen prior to testing.

Procedure of the test

1) Remove the test device from the foil pouch, and place it on a flat and dry surface.
2) Draw up the specimen using the disposable dropper.
3) Add one (1) drop (approximately 40㎕) of canine serum, plasma or whole blood into the sample hole, and then add four (4) drops (approximately 160㎕) of the assay diluent as shown in the figure below. If the migration has not appeared after 1 minute, add one more drop of the assay diluent to the sample well.
4) As the test begins to work, you will see a purple color move across the result window in the center of the test device.
5) Interpret test results at 5-10 minutes. Do not decide after 10 minutes.

[Figure for test Procedure]

Add 1 drop of sample | Add 4 drops of assay diluent | Read the results after 5-10 minutes

Interpretation of the test

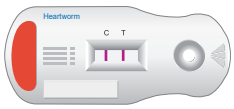
A colored band "C" will appear in the left section of the result window to show that the test is working properly. This band is the control band. The right section of the result window indicates the test results.

1) Negative result

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

2) Positive result

The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result.



3) Invalid result

If the control purple colored band ("C") is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

Limitations of the test

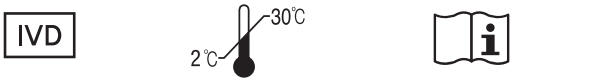
When using the Anigen Rapid Canine Heartworm Antigen Test kit to detect Canine *Dirofilaria immitis* antigen, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the veterinarian after all clinical and laboratory findings have been evaluated.

In a study conducted in the US, the kit showed a specificity of 100% and a sensitivity of 96.4%. In samples with "2 or more female worms" recovered at necropsy, the sensitivity was 100%. In a separate multicentric field trial study conducted in the US, the sensitivity and specificity were found to be 100%. In a study conducted using samples containing "1-3 male worms" or "one or more male worms mixed with adolescent worms" recovered at necropsy, the sensitivity was 100%.

Bibliography

1) Charles H, Courtney and John A. Cornell: Evaluation of heartworm immunodiagnostic test; JAVMA 197(6), 1990, 724-729
2) Charles H, Courtney, Qi-Yun Zeng: Comparison of heartworm antigen test kit performance in dogs having low heartworm burdens; Veterinary Parasitology, 96, 2001, 317-322
3) William M. O. Boto, Kendal G. Powers and David A. Levy: Antigens of *Dirofilaria immitis* which are immunogenic in the canine host: detection by immune-staining of protein blots with the antibodies of occult dogs; J. Immunol., 133(2), 1984, 975-980
4) Matsumura, K.,Kazuta, Y.,Endo, R, Tanaka.K.,Inoue, T.,and Matsuda. H: A microassay for dirofilarial antibodies by using antigen-coated nitrocellulose paper; Vet. Parasitol., 27, 1988, 337-344
5) John P. Thilsted, Jerry Whorton, Clair M, Hibbs, Gregory P, Jillson, Rick Steece and Mary Stromei: Comparison of four serotests for the detection of Dirofilaria immitis in dogs; Am. J. Vet.Res., 48(5), 1987, 837-841
6) L.C. Wang: Comparison of a whole blood agglutination test and ELISA for the detection of the antigens of *Dirofilaria immitis* in dogs; Ann Trop Med Parasitol, 92(1), 1998, 73-77

Key for symbols on box



In vitro diagnostic | Store between 2-30°C | Read insert for full information

Doc. No.: I1114-5E
Issued date: Feb. 14, 2018

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