Anigen Rapid ONE-STEP
Canine Heartworm Antigen Test Kit

Principles
The Anigen Rapid one-step 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 one-step 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 one-step Canine Heartworm Antigen Test Kit to identify Canine *Dirofilaria immitis* antigen in canine serum, plasma, or whole blood with a high degree of accuracy.

Materials provided (10 tests/kit or 100 tests/kit)
1) Ten (10) or one hundred (100) Anigen Rapid one-step Canine Heartworm Antigen test devices
2) Ten (10) or one hundred (100) disposable droppers for specimen
3) One (1) Instruction for use

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.
10) Do not mix components from different lot numbers.

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).
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.
3) 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 two (2) drops (approximately 80μl) of canine serum, plasma or whole blood into the sample hole. If the migration has not appeared after 1 minute, add one more drop into 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 20 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 band “C” within the result window indicates a negative result.

2) Positive result
The presence of two colored bands (“T” and “C”) 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
Although the Anigen Rapid one-step Canine Heartworm Antigen Test kit is very accurate in detecting 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% (54/54) and a sensitivity of 96.4% (53/55). In samples with “2 or more female worms” recovered at necropsy, the sensitivity was 100% (41/41). In a separate multicentric field trial conducted in the US, the sensitivity (15/15) and specificity (5/5) were found to be 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
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 Top Med Parasitol., 92(1), 1998, 73~77

Key for symbols on box:

![Box with symbols]

In vitro diagnostic
Store between 2~30°C
Read insert for full information.

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Manufactured by
BioNote, Inc.
2-9, Seo-gu-dong, Hwaseong-gu, Gyeonggi-do, Korea (445-170)
Tel: +82-31-211-0516, Fax: +82-31-803-4618,
bionote@bionote.co.kr
http://www.bionote.co.kr

Manufactured for
Modern Veterinary Therapeutics, LLC
18001 Old Cutler Road, Suite 317
Miami, Florida 33157 - USA
Tel: +1 305 234 8228 Fax: +1 305 503 8385
info@modernveterinatytherapeutics.com
http://www.modernveterinarytherapeutics.com

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