Anigen Rapid Heartworm Ag Test Kit 2.0

**Principles**

The Rapid Heartworm Ag Test Kit 2.0 is a chromatographic immunoassay for the qualitative detection of Canine *Dirofilaria immitis* antigen in canine serum, plasma, or whole blood. The Rapid Heartworm Ag Test Kit 2.0 has the letter “F” and “C” as test line and control line on the surface of the device. Both the test line and control line in the result window are not visible before applying any samples. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working. A purple test line will be visible in the result window if there is enough heartworm antigen 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 Rapid Heartworm Ag Test Kit 2.0 to identify Canine *Dirofilaria immitis* antigen in canine serum, plasma, or whole blood with a high degree of accuracy.

**Materials provided (10 tests/kit)**

1) Ten(10) Rapid HeartWorm Ag Test Kits.
2) Ten(10) Disposable droppers for specimen.
3) One(1) Instruction for use.
4) Ten(10) Anticoagulant tube.

**Precautions**

1) For veterinary diagnostic use only.
2) For the best results, strict adherence to the instructions is required.
3) All specimens should be handled as being potentially infectious.
4) Do not open or remove test kit from their individually sealed pouches until immediately before use.
5) Do not use the test kit if the pouch is damaged or the seal is broken.
6) Do not reuse test kit.
7) All reagents must be at room temperature before running 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.

**Storage and Stability**

The kit can be stored at room temperature or refrigerated (2~30℃). 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 should be used to serum, plasma, or whole blood (anticoagulated).

**[Whole blood]**

(1) Blood should be collected by a disposable syringe to tube treated with anticoagulant (Heparin, EDTA, or Citrate).
(2) Collected blood should be tested immediately or for up to 4 hours at room temperature. It may be stored at 2~8℃ for 24 hours.
(3) Severe hemolytic blood may affect the result.

**[Plasma]**

(1) Blood should be collected by a disposable syringe to tube treated with anticoagulant (Heparin, EDTA, or Citrate). And then separate plasma by centrifugation.
(2) Plasma may be stored at 2~8℃ for up to 2 weeks, for longer storage (1 year), freeze at or below -20℃.

**[Serum]**

(1) Blood should be collected by a disposable syringe to tube non-treated anticoagulant (Heparin, EDTA, or Citrate).
(2) Collected blood should be left at room temperature for 30 minutes for coagulation.
(3) Serum may be stored at 2~8℃ for up to 2 weeks, for longer storage (1 year), freeze at or below -20℃.
(4) If the test kit and specimens are stored refrigerated, they should be brought to room temperature prior to use.

**Procedure of the test**

1) Remove the test device from the foil pouch, and place it on a flat and dry surface.
2) Collect some sample using the disposable dropper.
3) Add 2 drops (approximately 80ul) of canine serum, plasma or whole blood into the sample hole.
4) As the test begins to work, you will see purple color move across the result window in the center of the test device.
5) Interpret test results at 5~10 minutes. Do not interpret after 10 minutes.

**Test Procedure**

1. Serum, plasma or whole blood.
   2. Add 2 drops into the sample hole.

**Interpretation of the test**

A color band will appear in the left section of the result window to show that the test is working properly, this is the Control band. The right section of the Result Window indicates the Test band, and if another color band appears immediately, then the test is considered invalid. The purple test band appears first indicates a positive test result.

1) Negative result
   - The presence of only one band within the result window indicates a negative result.

2) Positive result
   - The presence of two color bands (“T” and “C”) within the result window indicates a positive result.

3) Invalid result
   - If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may have been followed incorrectly or the test may have deteriorated. It is recommended to re-tested.

**Limitations of the test**

Although the Rapid Canine Heartworm Ag Test kit 2.0 is very accurate in detecting Canine heartworm 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.