

## One-Step Heartworm Antigen Test

### Rapide - *Dirofilaria Ag* Test Kit

Dirofilariasis in dogs and cats is a helminthiasis caused by *Dirofilaria immitis*, a parasite transmitted by mosquito's bites.

#### ■ Principles

The **Rapide - *Dirofilaria Ag* Test Kit** is a chromatographic immunoassay for the qualitative detection of *Dirofilaria immitis* antigen in serum, plasma, or whole blood.

The **Rapide - *Dirofilaria Ag* Test Kit** has the letter "T" 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. The control line should always appear if the test procedure is performed properly and the test reagents 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 *Dirofilaria immitis* antibodies are used in the test band as both capture and detector materials. These enable the **Rapide - *Dirofilaria Ag* Test Kit** to identify *Dirofilaria immitis* antigen in serum, plasma, or whole blood with a high degree of accuracy.

#### ■ Materials provided (10 tests/kit)

- 1) Ten(10) **Rapide - *Dirofilaria Ag* Test Devices.**
- 2) Ten(10) Disposable droppers for specimens.
- 3) One(1) Instruction for use.
- 4) Ten(10) Anticoagulant tubes.

#### ■ 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 kits 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 kits.
- 7) All reagents must be at room temperature (15°C~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.

#### ■ Storage and Stability

The kit can be stored at room temperature or refrigerated (2°C~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

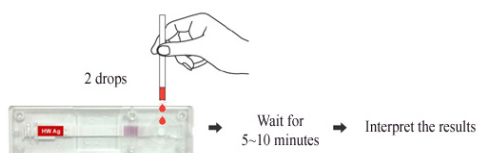
- 1) The test can be performed with serum, plasma, or whole blood.
- 2) If specimens are not immediately tested, they should be refrigerated at 2°C~8°C. For storage of more than 48 hours, freeze the specimen at -10°C or below.

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 two (2) drops (approximately 80ul) of serum, plasma or whole blood into the sample hole.
- 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. If the migration has not appeared after 1 minute, add one more drop to the sample well.
- 5) **Interpret test results at 5 ~ 10 minutes. Do not interpret after 10 minutes.**

[Figure for test procedure]



#### ■ Interpretation of the test

A colored band will appear in the left section of the result window (band "C") to show that the test is working properly. This band is the Control band. The right section of the result window indicates the test result. If another colored band appears in the right section of the result window, it is the test band.

#### 1) Negative result

The presence of only one colored 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 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.



#### ■ Performance

- Two large scale studies using 109 samples in the first and 174 in the second were conducted. The sensitivity was 96.4% and the specificity was 100% in the first study; the sensitivity was 94.4% and the specificity was 100% in the second study.
- In a multicentric field trial study conducted in the US, the sensitivity and specificity were found to be 100%.
- In a study conducted using samples obtained from animals for which adult male worms alone or mixed with adolescent worms but without any adult female worms were recovered at necropsy, the sensitivity was 100%.

#### ■ Limitations of the test

Although **Rapide - *Dirofilaria Ag* Test Kit** is very accurate in detecting *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.

#### ■ Bibliography

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