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

Materials provided (10 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) Ten (10) or one hundred (100) vials of EDTA
4) One (1) Instructions 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 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°C to 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 to 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). When using the included EDTA tubes, you should first collect the
   blood sample in a syringe and then put into the EDTA tube. Mix this around before
   using disposable dropper to draw the sample out and drop into the test device.
2) If specimens are not immediately tested, they should be refrigerated at 2°C to 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 two (2) drop (approximately 80 µl) 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 purple color band 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
Although the Anigen Rapid one-step Canine Heartworm Antigen Test kit is very
accurate in detecting Canine Dirofilaria immitis antigens, 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 study
conducted in the US, the sensitivity (15/15) and specificity (5/5) were found to be
100%.

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Key for symbols on box

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