Canine Heartworm Antigen Test Kit

Principles
The 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.

Specimen Collection and Preparation
The 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.

Storage and Stability
The specially selected Canine *Dirofilaria immitis* antibodies are used in the test band as both capture and detector materials. These enable the 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) Canine Heartworm Antigen Test Kits
2) One (1) or ten (10) bottle(s) containing 3ml of assay diluent
3) Ten (10) or one hundred (100) disposable droppers for specimen
4) 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 kit from their individually sealed pouches until immediately before their 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 (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.

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*Procedure of the test*
1) Remove the test device from the foil pouch, and place it on a flat and dry surface.
2) If specimens are not immediately tested, they should be refrigerated at 2~8°C before running the assay.
3) Blood samples should not be frozen prior to testing.
4) Do not open or remove test kit from their individually sealed pouches until immediately before their use.
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Storage and Stability
The kit can be stored at room temperature or refrigerated (2~30°C). The kit can be stored at room temperature or refrigerated (2~30°C). The test kit is stable before running the assay.

Limitations of the test
Although the 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% 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
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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
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