Canine Leishmania Antibody, Anaplasma ANA Antibody, Ehrlichia EHR Antibody, Heartworm CHW Antigen

AffiVET® Rapid Test Kit

AFG-VR-35

10 Tests

Material Required

(10) Rapid CaniV-4(Leish) Test Device
(10) Disposable Capillary Tube (20 µL)
(10) Anticoagulant tubes
(01) Assay Diluent Bottle
(01) Instruction of Use
(01) Timer, Micropipette (Not Provided)

The black line is the indicator line for 20 µL

Storage

1. Store the test kit at 2~30 ℃. **DO NOT FREEZE.**
2. Avoid direct Sunlight.
3. The test kit remains stable until the expiration date indicated on the package label.

Principle

- The AffiVET® Canine Leishmania Antibody, Anaplasma ANA Antibody, Ehrlichia EHR Antibody, Heartworm CHW Antigen [CaniV-4(Leish)] Rapid Test Kit employs Chromatographic Immunoassay technology for the qualitative detection of *Dirofilaria immitis* antigen, *Ehrlichia canis* antibody, *Leishmania infantum* antibody, and *Anaplasma phagocytophilum/Anaplasma platys* antibody in canine serum, plasma, or whole blood.
- The AffiVET® CaniV-4(Leish) Rapid Test Kit features two lines, the test line ("T") and control line ("C"), on the device's surface. Both lines are initially invisible before applying any samples. The control line serves as a reference to ensure proper test performance and must appear consistently with every test conducted. If the target antigens or antibodies are present in the sample, a purple test line will appear in the result window.
- Highly selective recombinant antigens or antibodies are utilized as capture or detector agents in the assay. These components demonstrate exceptional accuracy in detecting *Dirofilaria immitis* antigen (HW Ag), *Ehrlichia canis* antibody (E.canis Ab), *Leishmania infantum* antibody (Leishmania Ab), and *Anaplasma phagocytophilum/Anaplasma platys* antibody (Anaplasma Ab) in canine samples.

Precautions

1. Utilize the test kit exclusively for canine specimens; refrain from application on other animals.
2. Conduct the test immediately after removing the test device from the foil pouch, as the device is sensitive to humidity and heat.
3. Avoid reusing the test components to ensure accurate results.
4. Administer the sample vertically using a dropper or capillary tube.
5. Refrain from touching the membrane in the result window of the test device.
6. Adhere strictly to the stated expiration date marked on the package label; do not use the test kit beyond this date.
7. Discard the test kit if the pouch is damaged or the seal is broken.
8. Avoid mixing components from different lot numbers, as the components undergo quality control testing as standard batch units.
9. Handle all samples as potentially infectious; wear protective gloves during sample manipulation and wash hands thoroughly afterward.
10. Ensure safe decontamination and disposal of all samples, used kits, and potentially contaminated materials in compliance with national and local regulations.

Sample
Collection & Preparation

1) Whole blood, serum, or plasma should be for this test.

Whole blood

Gather whole blood into the provided anticoagulant tube (Max. vol. 1.5ml). If anticoagulated whole blood is not immediately tested, refrigerate at 2~8°C and use within 24 hours.

Serum

Collect whole blood into a collection tube devoid of anticoagulants such as heparin, EDTA, and sodium citrate. Allow the blood to settle for 30 minutes for coagulation, then centrifuge to obtain supernatant.

Plasma

Acquire whole blood into a collection tube containing anticoagulants such as heparin, EDTA, or sodium citrate. Subsequently, centrifuge the blood to obtain plasma.

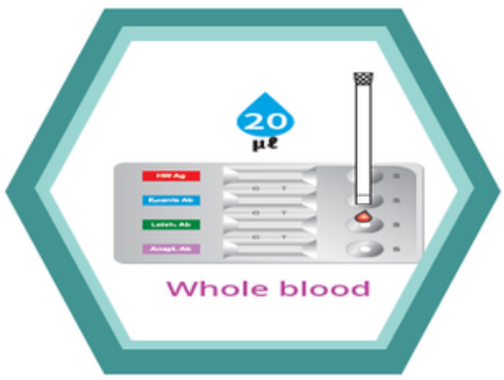
2) Store serum samples at 2~8°C. For extended storage, freeze the samples at -20°C or below. Prevent repeated freezing and thawing cycles.

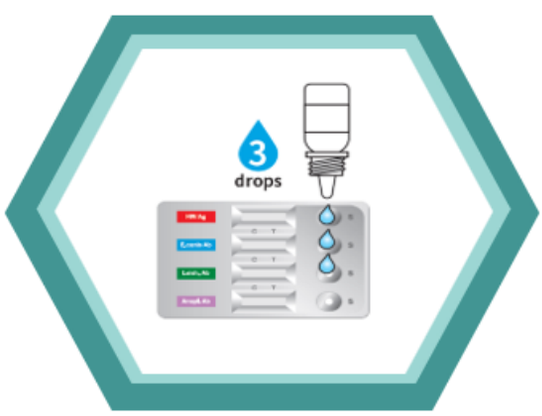
3) Samples containing precipitate may produce inconsistent test results and must be clarified before assaying.

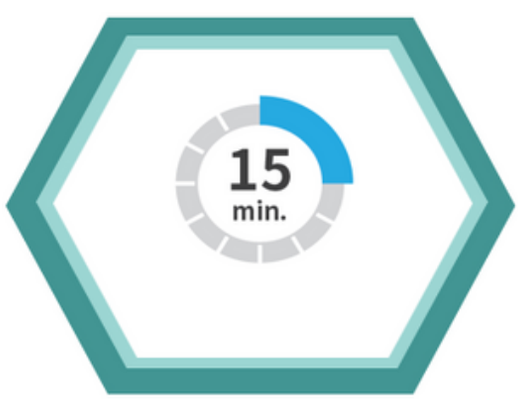
4) Hemolyzed or contaminated samples may lead to erroneous results.

Test Procedure

1. Ensure all reagents and samples are at room temperature (15~30°C) before proceeding.
2. Remove the test device from the foil pouch and place it on a flat, dry surface.
3. Using a disposable capillary tube, dispense 20 µL of whole blood into each sample hole (S) of the test device. Alternatively, add 10 µL of serum/plasma into each sample hole using a micropipette.
4. Add 3 drops of assay diluent into each sample hole (S).
5. Start the timer. The sample will migrate across the result window. If it does not appear after 1 minute, add one more drop of assay diluent to the sample hole.
6. Interpret test results precisely at 15 minutes. Avoid interpretation after 25 minutes.

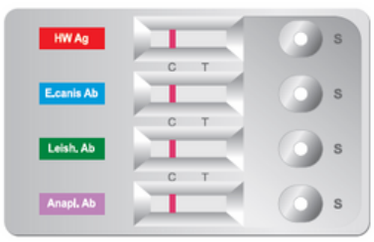






Result Interpretation

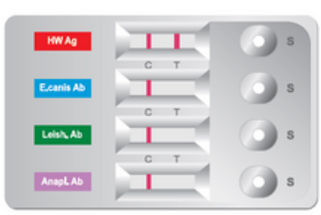
- Negative Result
  - Only control line (“C”) appears in the result window.



- Positive Result

- Test line (“T”) and control line (“C”) within the result window indicate the presence of target antigens and/or antibodies.

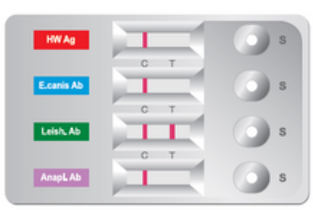
CHW Ag Positive



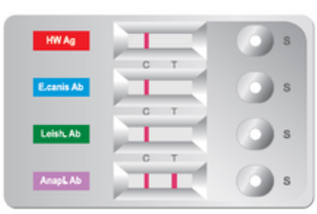
E.canis Ab Positive

* NOTE: Test strip of Anaplasma Ab can't differentiate between *A.phagocytophilum* and *A.platys*: a positive result indicates presence of antibodies to *A. phagocytophilum* and/or *A. platys*

Leishmania Ab Positive

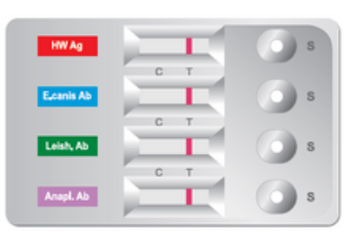


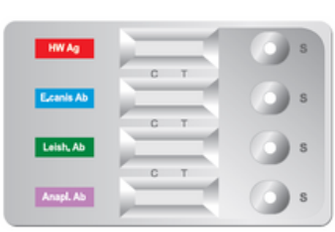
Anaplasma Ab Positive



- Invalid Result

- If the control line (“C”) does not appear, the result might be considered invalid. The sample should be retested.





Limitations

1) While The AffiVET® CaniV-4(Leish) Rapid Test kit is highly accurate in detecting *Dirofilaria immitis* antigen, *Ehrlichia canis* antibody, *Leishmania infantum* antibody and *Anaplasma phagocytophilum/Anaplasma platys* antibody, occasional false results may occur. In cases of uncertainty, additional clinical or laboratory tests may be necessary. A conclusive clinical diagnosis should rely on thorough evaluation by a veterinarian, considering all clinical and laboratory findings, rather than solely on the result of a single test.

2) The reading window may exhibit a light pink background coloration, which does not compromise the accuracy of the results.

3) AffiGEN Inc. and its distributors cannot be held liable for any consequences resulting from the misuse or misinterpretation of the test results.

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