

**Canine Lyme Antibody,
Anaplasma ANA Antibody,
Ehrlichia EHR Antibody,
Heartworm CHW
Antigen**

AffIVET® Rapid Test Kit

AFG-VR-36 - 10 Tests

AFG-VR-37- 5 Tests



Material Required

(10/5) Rapid Canine Lyme Antibody, Anaplasma ANA Antibody, Ehrlichia EHR Antibody, Heartworm CHW Ag Test Device

(10/5) Assay Diluent Tube

(10/5) Anticoagulant tube

(10/5) Disposable Capillary Tube (20 μ L)

(01) Instruction of Use

(01) Timer (Not Provided)

(01) Micropipette (Not Provided)

A black line on the capillary tube is the indicator line for 10 μ L.



Storage

- 1) Store the test kit at 2~30°C. **DO NOT FREEZE.**
- 2) Do not store the test kit in the direct sunlight.
- 3) The test kit is stable within the expiration date marked on the package label.

Principle

- The AffiVET® Canine Lyme Antibody, Anaplasma ANA Antibody, Ehrlichia EHR Antibody, Heartworm CHW Antigen Rapid Test Kit employs a chromatographic immunoassay technique to qualitatively detect antigens and antibodies associated with *Dirofilaria immitis*, *Ehrlichia canis*, *Borrelia burgdorferi*, and *Anaplasma phagocytophilum*/*Anaplasma platys* in canine serum, plasma, or whole blood.
- This kit consists of a device featuring two lines: the test ("T") line and the control ("C") line. Initially, these lines are not visible. The appearance of the control line serves as a reference, indicating proper test performance. It should always appear after testing. If the sample contains the target antigens or antibodies, a purple test line will also appear in the result window.
- The assay employs highly selective recombinant antigens or antibodies as capture or detector molecules. These molecules specifically target *Dirofilaria immitis* antigen (HW Ag), *Ehrlichia canis* antibody (E.canis Ab), *Borrelia burgdorferi* antibody (Lyme Ab), and *Anaplasma phagocytophilum*/*Anaplasma platys* antibody (Anaplasma Ab) in canine samples, ensuring high accuracy in detection.



Precautions

1. Use the test kit exclusively for canine specimens; refrain from application on other animals.
2. Exercise caution regarding humidity and heat sensitivity of the test device; conduct the test promptly upon removal from the foil pouch.
3. Avoid reusing test components to maintain accuracy.
4. Apply samples and assay diluents vertically to ensure precise results.
5. Refrain from touching the membrane within the result window of the test device.
6. Adhere strictly to the stated expiration date on the package label; avoid using the test kit beyond this date.
7. Discard the test kit if the pouch shows signs of damage or if the seal is compromised.
8. Refrain from combining components from different lot numbers; all kit components have been quality control tested as standard batch units.
9. Handle all samples as potentially infectious; wear protective gloves during sample manipulation and wash hands thoroughly afterward.
10. Safely decontaminate and dispose of all samples, reaction kits, and potentially contaminated materials according to national and local regulations.

Sample Collection & Preparation

1) This test requires whole blood, serum, or plasma.

Whole blood

- Collect whole blood into the provided anticoagulant tube (maximum volume 1.5 ml). If anticoagulated whole blood is not immediately tested, it should be refrigerated at 2~8°C and used within 24 hours.

Serum

- Collect whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate), let it settle for 30 minutes for blood coagulation, and then centrifuge to obtain the supernatant.

Plasma

- Collect whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) and then centrifuge to obtain plasma.

2) Serum samples should be stored at 2~8°C. For longer storage, freeze the samples at -20°C or below. Avoid repeated freezing and thawing.

3) Samples containing precipitate may yield inconsistent test results. They must be clarified before assaying.

4) Hemolyzed or contaminated samples may give erroneous results. Therefore, ensure sample purity by carefully assessing sample integrity. If hemolysis or contamination is detected, take corrective measures such as recollection or sample purification to avoid erroneous results.

Test Procedure

1. Ensure that all reagents and samples are equilibrated to room temperature (15~30°C) prior to initiating the assay.

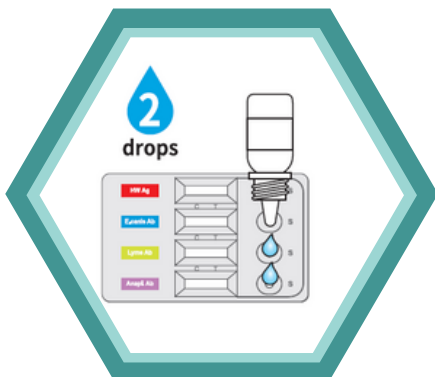
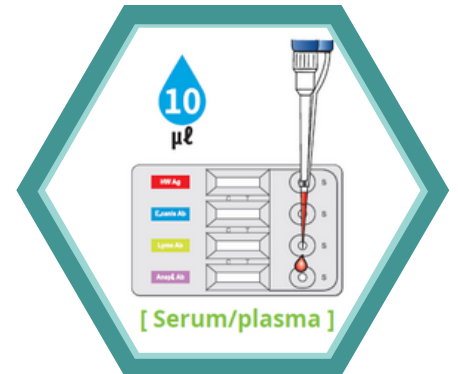
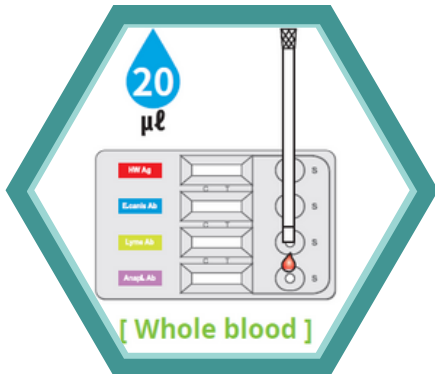
2. Take out the test device from the foil pouch and position it on a flat, dry surface.

3. Using either a disposable capillary tube, add 20 μl of whole blood into each sample hole. Alternatively, use a micropipette to add 10 μl of serum/plasma into each sample hole.

4. Dispense 2 drops of assay diluent into every sample hole.

5. Begin the timer. The sample will migrate across the result window. If no result appears after 1 minute, add an extra drop of assay diluent to the sample hole.

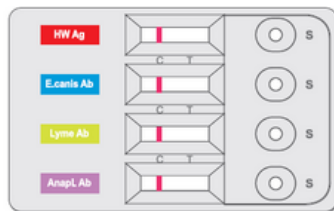
6. Read and interpret the test results precisely at the 15-minute mark. Do not analyze the results after this designated time.



Result Interpretation

- Negative Result

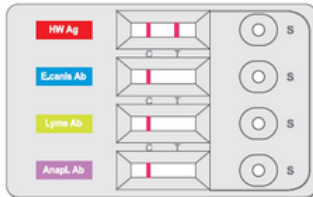
- Presence of C-Line
- Absence of T-Line



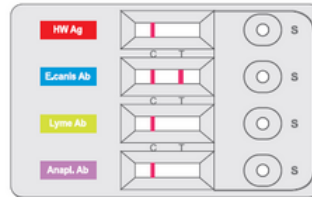
- Positive Result

- Presence of C-Line
- Presence of T-Line

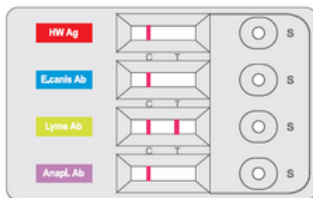
HW Ag Positive



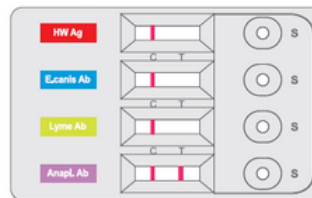
E.canis Ab Positive



Lyme Ab Positive

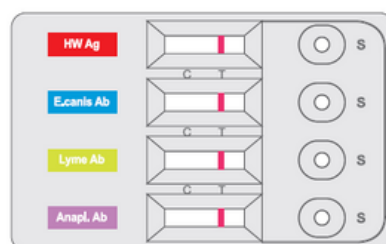
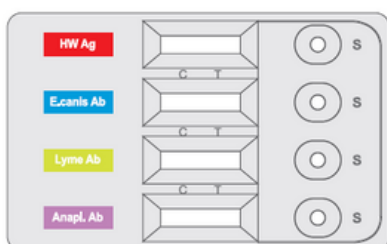


Anaplasma Ab Positive



- Invalid Result

- Absence of C-Line and Presence of T-Line
- or
- Absence of C-Line and Absence of T-Line



Limitations

1. While the AffiVET® Canine Lyme Antibody, Anaplasma ANA Antibody, Ehrlichia EHR Antibody, Heartworm CHW Antigen Rapid Test Kit is highly accurate in detecting *Dirofilaria immitis* antigen, Ehrlichia canis antibody, Borrelia burgdorferi antibody, and Anaplasma phagocytophilum/Anaplasma platys antibody, occasional false results may occur. In cases of questionable results, additional clinical and/or laboratory tests may be necessary. It is important to note that a definitive clinical diagnosis should not rely solely on the outcome of a single test but should be determined by the veterinarian after evaluating all clinical and laboratory findings.
2. The reading window may exhibit a light pink background coloration; however, this will not impact the accuracy of the results.
3. AffiGEN and its distributors cannot be held liable for the repercussions of misuse or misinterpretation of the test results.

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