

Anigen Rapid FIV Ab Test Kit

1. Explanation of the test

The Anigen Rapid FIV Ab Test Kit is a chromatographic immunoassay kit for the qualitative detection of Feline Immunodeficiency Virus Antibody in feline serum, plasma or whole blood.

FIV is a lentivirus of domestic and wild cats that has been shown to occur world-wide. It has a prevalence between 1% and over 30% depending on the area and the cat population. Similar to the human counterpart, the HIV causing AIDS, after a long period of infection FIV induces immunosuppressive diseases. Among the most important clinical signs are gingivitis/stomatitis, diarrhea, lymphadenopathy, fever, anemia and leukopenia. So far, there is no easy treatment known and infected cats will die after weeks to months after clinical signs have developed.

The Anigen Rapid FIV Ab Test Kit test device has a letter T and C as "Test Line" and "Control Line" on the surface of the case. 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 and should always appear if the test procedure is performed properly, and the test reagents of the control line are working. A purple "Test Line" will be visible in the result window if there is antibody against FIV in the specimen.

The specially selected recombinant FIV p24 & gp40 antigens are used in the test strip as both capture and detector materials. These enable the Anigen Rapid FIV Ab Test Kit test to identify FIV antibody in specimens with a high degree of accuracy.

2. Materials provided (10 tests/kit)

Anigen Rapid FIV Ab Test Kit contains following items to perform the assay

- 1) Ten(10) Anigen Rapid FIV Ab Tests
- 2) One (1) Assay Diluent bottle
- 3) Ten (10) Disposable Capillary tube for specimens
- 4) Ten (10) Anticoagulant bottles
- 5) One (1) Instructions for use

♣ A dark color score line on the capillary tube is the indicator line for 10ul.



3. Precaution

- 1) For veterinary diagnostic use only.
- 2) For 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 the test kits 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 kits.
- 7) All reagents must be at room temperature 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 a standard batch unit. Do not mix components from different lot numbers.

4. Storage and Stability

The kit can be stored at room temperature (2~30°C) or refrigerated. 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.

5. Specimen Collection and Storage

- 1) The test should be performed using serum, plasma, or whole blood.
- 2) [Whole blood]

Collect an anticoagulated blood sample in EDTA, heparin or citrate using standard clinical laboratory procedures. Anticoagulated whole blood samples should be tested within 24 hours of drawing. If delays in testing are expected, samples should be stored either on ice or refrigerated(2~7°C), but should not be frozen. If anticoagulated whole blood samples cannot be tested within this period of time, separate the plasma by centrifugation and store as described in the next section.
- 3) [Plasma]

Collect an anticoagulated blood sample using standard clinical laboratory procedures. Separate plasma by centrifugation. Plasma samples may be stored refrigerated(2~7°C) for up to 72 hours; for longer storage, freeze at or below -20°C in vials with air-tight seals.
- 4) [Serum]

Collect and prepare serum samples using standard clinical laboratory procedures. Serum samples may be stored refrigerated (2~7°C) for up to 72 hours; for longer storage, freeze at or below -20°C in vials with air-tight seals.

4. Procedure of the test

- 1) Remove the test device from the foil pouch, and place it on a flat and dry surface.
- 2) Using the disposable capillary tube, add one (1) drop (approximately 10ul) of feline serum, plasma or whole blood into the sample hole, and then add two (2) drops (approximately 60ul) of the assay diluents.
- 3) 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 of the assay diluent to the sample well.
- 4) Interpret test results at 10 minutes. Do not interpret after 10 minutes.

5. Interpretation of the test

- 1) A color band will appear in the left section of the result window to show that the test is working properly. This band is the Control Band.
- 2) The right section of the result window indicates the test results. If another color band appears in the right section of the result window, this band is the Test Band.

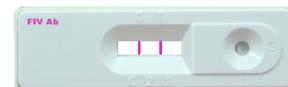
Negative result

The presence of only one band within the result window indicates a negative result.



Positive result

The presence of two color bands ("T" and "C") within the result window, no matter which band appears first indicates a positive result.



Invalid result

If the purple color band 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.



6. Limitations of the test

Although the Anigen Rapid FIV Ab Test Kit Test is very accurate in detecting FIV antibody, 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.

7. Expected Values

The Anigen Rapid FIV Ab Test Kit has been compared with a leading commercial FIV Ab test. The overall accuracy is greater or equal to 99.0%

8. Bibliography of suggested reading

- 1) Calzolari M., Young E., Cox D., Davis D., Lutz H. Serological diagnosis of feline immunodeficiency virus infection using recombinant transmembrane glycoprotein. *Vet.Immunol. Immunopathol.* 46, 83-92 (1995).
- 2) Lutz H. Feline retroviruses: a brief review. *Vet. Microbiol-ogy* 23, 131-146 (1990).
- 3) Pedersen N.C., Yamamoto J.K., Ishida T., Hansen H., Feline immunodeficiency virus. *Vet.Immunol.Immunopathol.* 21, 111-129 (1989).
- 4) Pedersen N.C., Torten M., Rideout B., Sparger E., Tona-chini T., Luciw P.A., Ackley C., Levy N., Yamamoto J. Fe-line leukemia virus infection as a potentiating cofactor for the primary and secondary stages of experimentally induced feline immunodeficiency virus infection *J.Virol.* 64, 598-606, (1990).

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