

One Step Feline Leukemia virus RAPID TEST

Anigen Rapid FeLV Ag Test Kit

1. Explanation of the Test

Feline Leukemia Virus (FeLV) is a retrovirus that can directly cause cancer. The virus is usually transmitted through contact with the saliva of an infected cat. Kittens under 16 weeks are the most susceptible to the virus. Cats over 16 weeks who are dealing with an illness unrelated to FeLV, stress, or injury may also be more susceptible. Diseases caused by FeLV include lympho-sarcoma, myelogenous leukemia, thymic atrophy, nonregenerative anemia and panlukopenia-like disease. Because FeLV is immunosuppressive, it predisposes infected cats to variety of secondary diseases. The FeLV is excreted in saliva and tears and possibly the urine and feces of infected cats. Prolonged, extensive cat-to-cat contact is required for efficient spread, because the virus is rapidly inactivated by warmth and drying.

The Anigen Rapid FeLV Ag Test Kit is a chromatographic immunoassay for the qualitative detection of FeLV antigen in feline whole blood, plasma or serum.

The Anigen Rapid FeLV Ag Test Kit has a letter of T and C as “Test Line” and “Control Line” on the surface of the kit. Both the “Test Line” and “Control Line” in result window are not visible before applying any samples. The “Control Lines” is used for procedural control. Control line should always appear if this procedure is performed properly and the test reagents of control line are working. A purple “Test Line” will be visible in the result window if there are enough FeLV antigens in the specimen.

The specially selected FeLV antibodies are used in test and as both capture and detector materials. These enable the Anigen Rapid FeLV Ag Test Kit to identify to FeLV antigen in specimens, with a high degree of accuracy.

2. Materials Provided

Anigen Rapid FeLV Ag Test Kit contains following items to perform the assay.

- 1) Ten(10) Anigen Rapid FeLV Ag Tests
- 2) One(1) Assay Diluent bottle
- 3) Ten(10) Disposable droppers
- 4) One(1) Instructions for use

3. Storage and Stability

The Anigen Rapid FeLV Ag Test Kit should be stored at room temperature. The test device is sensitive to humidity and as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

4. Specimen Collection and Storage

- 1) [whole blood] Collect the whole blood using the suitable anti-coagulant.
- 2) [serum or plasma] Centrifuge whole blood to get plasma or serum specimen.
- 3) If specimens are not immediately tested they should be refrigerated at 2 ~ 8°C. For storage periods greater than three days, freeze the specimen at - 20°C or below. They should be brought to room temperature prior to use.

- 4) Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 5) Whole blood may be used for testing immediately or may be stored at 2 ~ 8°C up to three days.

5. Precautions

- 1) For *in-vitro* diagnostic use only.
- 2) Do not eat or smoke while handling specimens.
- 3) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 4) Avoid splashing or aerosol formation.
- 5) Clean up spills thoroughly using an appropriate disinfectant.
- 6) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 7) Do not use the test kit if the pouch is damaged or the seal is broken.

6. Test Procedure

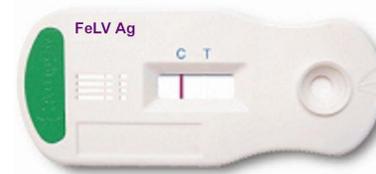
- 1) Remove the test kit from the foil pouch, and place it on a flat, dry surface.
- 2) Slowly add one drop of serum, plasma or whole blood to the sample well with specimen dropper and then add 4 drops with bottle containing diluent buffer.
- 3) As the test result, you can see the purple band in the result window of the kit.
If the migration has not appeared after 1 minute, add one more drop of Assay diluent to the sample well.
- 4) Interpret test results at 5 ~ 10 minutes. Do not interpret after 20 minutes.

Caution: The above interpreting time is based on reading the test results at room temperature of 15 ~ 30°C. If your room temperature is significantly no more than 15°C, then the interpreting time should be properly increased.

7. 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 line(“C”).
- 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 line(“T”).

Negative : The presence of only one purple color band within the result window indicates a negative result.



Positive : 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.



Invalid : 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.



8. Limitations of the Test

- 1) Anigen Rapid FeLV Ag Test Kit will only indicate the presence of FeLV in the specimen and should not be used as the sole criteria for the diagnosis of FeLV infection.
- 2) As with all diagnostic tests, all results must be interpreted together with other clinical information available to the veterinarian.
- 3) If the test result is negative and clinical symptom is persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of FeLV infection.

9. Expected Values

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

10. Bibliography of Suggested Reading

- 1) K. Hartemann, R.M.Werner, H.Egberink, O. Jarrett. Comparison of six in-house tests for the rapid diagnosis of feline immunodeficiency and feline leukaemia virus infections. *Veterinary Record*. 15:317-320. 2001.
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- 4) William D. Hardy, Jr., and Evelyn E. Zuckerman. Development of the immunofluorescent antibody test for detection of feline leukemia virus infection in cats. *J Am Vet Med Assoc*. 199(10):1327-1335, 1991.
- 5) William D. Hardy, Jr., and Evelyn E. Zuckerman. Ten-year study comparing enzyme-linked immunosorbent assay with the immunofluorescent antibody test for detection of feline leukemia virus infection in cats. *J Am Vet Med Assoc*. 199(10):1365-1373. 1991.

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