One Step Feline Leukemia Virus Antigen Detection Test

Rapide - FeLV Ag Test Kit

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 lymphosarcoma, myelogenous leukemia, thymic atrophy, nonregenerative anemia and pancytopenia-like disease. Because FeLV is immunosuppressive, it predisposes infected cats to a 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.

1. Principle
   The Rapide - FeLV Ag Test Kit is a chromatographic immunosorbasis for the qualitative detection of FeLV antigen in feline whole blood, plasma or serum. The Rapide - FeLV Ag Test Kit has the letters of T and C as “Test Line” and “Control Line” on the surface of the kit. 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 this 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 are FeLV antigens in the specimen.
   The specially selected FeLV antibodies are used in the test and as both capture and detector materials. These enable the Rapide - FeLV Ag Test Kit to identify FeLV antigen in specimens with a high degree of accuracy.

2. Materials Provided (10 tests/kit)
   1) Ten (10) Rapide - FeLV Ag Tests
   2) One (1) Assay Diluent bottle
   3) Ten (10) Disposable capillary tubes
   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 10μL.

3. Storage and Stability
   1) The Rapide - FeLV Ag Test Kit should be stored at room temperature or refrigerated (2~30°C). The test device is sensitive to humidity as well as to heat.
   2) Do NOT FREEZE. Do not store the test kit in direct sunlight.
   3) Perform the testing immediately after removing the test device from the foil pouch.
   4) Do not use it beyond the expiration.

4. Specimen Collections 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 are expected between sampling and testing, the sample 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 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.

   Note: Refrigerated and frozen samples should be brought to room temperature prior to use. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

5. Precautions
   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 (15°C – 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 a standard batch unit. Do not mix components from different lot numbers

6. Test Procedure
   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 10 μL) of feline serum, plasma or whole blood into the sample hole, and then add two (2) drops (approximately 60 μL) of the assay diluent.
   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 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 below 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 result. This band is the Test line (“T”).

   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 “C” 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
   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.

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