

Rapide - FCoV Ab Test Kit

Principles

The **Rapide - FCoV Ab Test Kit** is a chromatographic immunoassay for the qualitative detection of Feline Coronavirus (FCoV) antibodies in feline whole blood, serum, or plasma.

The **Rapide - FCoV Ab Test Kit** has a letter of "T" and "C" as test line and control line on the surface of the device. 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 correctly and the test reagents are working. A purple test line will be visible in the result window if Feline Coronavirus antibodies are present in the specimen.

The specially selected Feline Coronavirus antigens are used in the test band as both capture and detector materials. These enable the **Rapide - FCoV Ab Test Kit** to identify Feline Coronavirus antibodies in feline whole blood, serum, or plasma with a very high degree of accuracy.

Materials provided (10 tests/kit)

- 1) Ten(10) **Rapide - FCoV Ab Tests**.
 - 2) One(1) Bottle containing 3 ml of assay diluents.
 - 3) Ten(10) Disposable Capillary tube for specimens.
 - 4) One(1) Instructions for use.
- ♣ A dark color score line on the capillary tube is the indicator line for 10µL.



Precautions

- 1) For veterinary diagnostic use only.
 - 2) For best results, strict adherence to these instructions is required.
 - 3) All specimens should be handled as being potentially infectious.
 - 4) Do not open or remove test kit 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 kit.
 - 7) All reagents must be at room temperature (15–25°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 standard batch unit.
- Do not mix components from different lot numbers.

Storage and Stability

The kit can be stored at room temperature or refrigerated (2–30°C). The kit is stable through the expiration date marked on the package label. **DO NOT FREEZE**. Do not store the test kit in direct sunlight.

Specimen Collection and Preparation

- 1) The test should be performed using serum, plasma, or whole blood.
- 2) [Whole blood]: Collect an anticoagulated blood sample in EDTA, heparin for citrate using standard clinical laboratory procedures. Anticoagulated whole blood samples should be tested within 24 hours of drawing. If delays 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 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.

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 10µL) of feline serum, plasma or whole blood into the sample hole, and then add three (3) drops approximately 90 µL 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 20 minutes.

[Figure for test procedures]

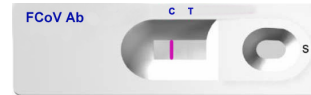


Interpretation of the test

A colored band will appear in the left section of the result window ("C" band) to show that the test is working properly. This band is the control band. The right section of the result window indicates the test results.

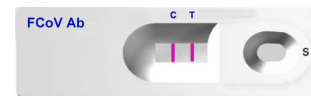
1) Negative result

The presence of only one band ("C") within the result window indicates a negative result.



2) 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.



3) Invalid Result

If the purple colored 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.



Performance data

In a study using 149 samples, **Rapide - FCoV Ab Test kit** was compared to Immuno-Fluorescence Antibody Test (IFA), a reference standard technique in laboratory diagnostics, the sensitivity was 96% and specificity was 97.9%. In another field trial study taking place at multiple veterinary clinics in the United States, the sensitivity and the specificity were 100% compared to IFA.

Limitations of the test

Although the **Rapide - FCoV Ab Test Kit** is very accurate for detecting Feline Coronavirus Antibodies, a low incidence of false results can occur. Other clinical 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.

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