For veterinary diagnostic use only

* Anigen Rapid FCV Ag Test Kit

Principles

The Anigen Rapid FCV Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Feline Calicivirus antigen in conjunctival. The Anigen Rapid FCV Ag Test Kit has two letters which are test ("T") line and control ("C") line on the surface of device. Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line has to appear every time when the test has performed. If the FCV antigens are present in sample, a purple test line would appear in the result window.

The highly selective antibodies to FCV are used as capture and detector in the assay. These antibodies are capable of detecting FCV antigen in feline samples with a high accuracy.

■ Materials provided

Materials	10 Tests/Kit
Anigen Rapid FCV Ag Test Device	10
Assay diluent tube	10
Disposable swab	10
Disposable dropper	10
Instructions for use	1

■ Materials required, but not provided

1) Timer

■ Precautions

- 1) The test kit is for feline use only. Do not use for other animals.
- The test device is sensitive to humidity as well as heat. Perform the test immediately after removing the test device from the foil pouch.
- 3) Do not reuse test components.
- 4) Apply the sample using disposable dropper vertically.
- 5) Do not touch the membrane in the result window of test device.
- 6) Do not use the test kit beyond the stated expiration date marked on the package label.
- 7) Do not use the test kit if the pouch is damaged or the seal is broken.
- 8) Do not mix components from different lot numbers because the components in this kit have been quality control tested as standard batch unit.
- 9) All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterward.
- Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.
- Strictly follow the test procedures to minimize false or invalid test results due to improper administration of the product usage or doses.

Storage and Stability

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

Collection and Preparation of Sample

- 1) Feline conjunctival sample should be used for this test.
- 2) The samples should be tested immediately after collection. If samples are not tested immediately, they should be stored at 2~8 °C for 24 hours. For longer storage, freeze at -20 °C or below. Frozen samples should be brought to room temperature (15~30 °C) prior to use.

■ Procedure of the Test

- 1) All reagents and samples must be at room temperature (15~30 $\,^{\circ}\text{C})$ before use.
- 2) Collect the samples.

[Conjunctival sample] Collect the samples using a swab. Insert the swab into the assay diluent tube and mix the swab for 10 seconds.



3) Wait for 1 minute to settle down the sample.



- Please remove the test device from the foil pouch, and place it on a flat and dry surface.
- 5) Add four (4) drops of the mixed sample into the sample hole using the dropper, drop by drop vertically.



- 6) Start the timer. The sample will flow across the result window. If it does not appear after 1 minute, add one more drop of mixed sample to the sample hole.
- 7) Interpret test results at 10 minutes.

 Do not read after 20 minutes.



■ Interpretation of the Result

1) Negative result

Only Control ("C") line appears in the result window.



2) Positive result

Test ("T") line and Control ("C") line in the result window indicate the presence of FCV antigen. $\label{eq:control} % \begin{center} \beg$



3) Invalid result

If the Control ("C") line does not appear, the result might be considered invalid. The sample should be retested.





■ Limitations of the Test

- 1) Although the Anigen Rapid FCV Ag Test kit is very accurate in detecting Feline Calicivirus antigen, 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.
- The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
- 3) BIONOTE Inc. and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

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