For veterinary diagnostic use only

Anigen Rapid CCV Ag Test Kit

Principles

The Anigen Rapid CCV Ag Test Kit is a chromatographic immunoassay for the qualitative detection of Canine Corona virus(CCV) antigen in canine feces. The Anigen Rapid CCV 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 CCV antigens are present in sample, a purple test line would appear in the result window. The highly selective antibodies to CCV are used as a capture and detector in the assay. These antibodies are capable of detecting CCV antigens in canine feces with high accuracy.

Materials provided

Materials	5 Tests/Kit	10 Tests/Kit
Anigen Rapid CCV Ag Test Device	5	10
Assay diluent tube	5	10
Disposable swab	5	10
Disposable dropper	5	10
Instructions for use	1	1

Materials required, but not provided

1) Timer

Precautions

- 1) The test kit is for canine use only. Do not use for other animals.
- 2) 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 afterwards.
- 10) Decontaminate and dispose of all samples, reaction kits and potentially contaminated materials safely in accordance with national and local regulations.

Storage and Stability

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

■ Collection and Preparation of Sample

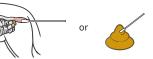
- 1) Canine feces swab should be used for this test.
- 2) The samples should be tested immediately after collection.
- 3) If samples are not tested immediately, they should be stored at 2~8°C for 24 hours. For longer storage, freeze at -20°C or below. Frozen samples should be brought to room temperature (15~30°C) prior to use.
- 4) The amount of fecal swab may affect the results. It is required to follow the swab amount of feces as shown in the picture on the below. Excessive fecal amount may induce a false positive result and slow migration.



■ Procedure of the Test

1) All reagents must be at room temperature (15~30°C) before use.

2) Collect feces samples using a swab.



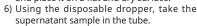
3) Insert the swab into the assay diluent tube and mix the swab until the sample has been dissolved into the assay diluent (Approximately 10sec).



4) Wait for 1 minute to settle down the large



5) Remove the test device from the foil pouch, and place it on a flat and dry surface.





7) Add four(4) drops of mixed sample into the sample hole(S), drop by drop vertically.



8) Start the timer. The sample will flow across the result window. If it does not appear after 1minute, add one more drop of mixed sample to the sample hole.



9) Interpret test results at 5~10 minutes. Do not read the result after 20 minutes.

■ Interpretation of the Result

1) Negative result

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



2) Positive result

Test ("T") line and control ("C") line within the result window indicate the presence of CCV antigen.



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 CCV Ag Test kit is very accurate in detecting Canine Coronavirus antigen, a low incidence of false results can be occurred. Other clinically or laboratory tests might be required if questionable results are obtained. As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be diagnosed by the veterinarian after all clinical and laboratory findings have been evaluated. The detection limit of this kit is about 1.97x10^{4.0}TCID₅₀/mℓ.
- 2) The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
- 3) BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the

Doc. No.: I1104-7E Revised date: Jun. 08. 2021

