Vcheck

FCoV Ag

FELINE CORONA VIRUS

For veterinary use only

INTENDED USE

The Vcheck FCoV Ag is an *in vitro* diagnostic test kit for the qualitative detection of Feline Corona virus(FCoV) antigen in Feline feces. The Vcheck FCoV Ag is designed to be used only by veterinarians.

PRINCIPLE

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

MATERIALS PROVIDED

Reagent	10 Tests/Kit
① Vcheck FCoV Ag Test device	10
② Assay diluent tube	10
③ Disposable swab	10
④ Pipette tip	10
⑤ Instructions for use	1

MATERIALS REQUIRED, BUT NOT PROVIDED

1. Timer
2. BIONOTE Vcheck Analyzer
3. 100 µℓ pipette

STORAGE AND STABILITY

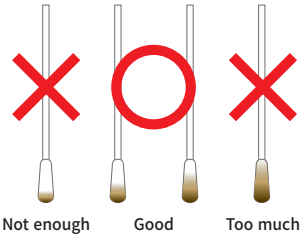
1. Store the test kit at 2~30℃. **DO NOT FREEZE.**
2. Do not store the test kit in the direct sunlight.
3. The test kit is stable within the expiration date that marked on the package label.

PRECAUTIONS

1. The test kit is for Feline 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 the test components.
4. Apply the sample using pipette 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.

COLLECTION AND PREPARATION OF SAMPLE

1. Feline 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 feces on the swab may affect results. The correct amount of feces is indicated in the picture below. An excessive amount of feces may cause a false positive result and slow sample migration.

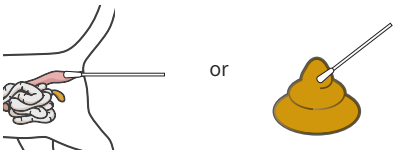


TEST PROCEDURE

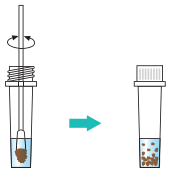
[Collect the samples]

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

1. Collect feces samples using a swab.



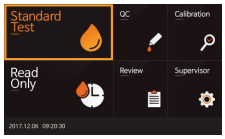
2. Insert the swab into the assay diluent tube and mix the swab until the sample has been dissolved into the assay diluent (Approximately 10sec).
3. Remove the swab, then wait for a minute to settle down the large particles.



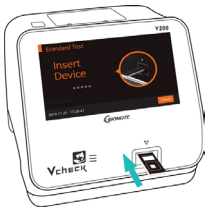
[Using a V200 Analyzer]

"Standard Test" mode

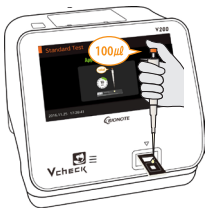
1. Turn on V200 Analyzer and select "Standard Test" on the analyzer's screen.
2. Remove the test device from the foil pouch.



3. Once the "Insert Device" is displayed in the screen, insert the test device into the V200 Analyzer.



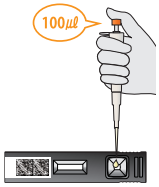
4. Use a 100 µℓ pipette to add 100 µℓ of mixed sample into the sample hole, and press **[START]** to initiate testing.



5. Read the result on the display after 10 minutes.
6. The V200 analyzer will automatically display the test result on the screen.
7. Remove the test device.

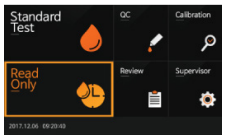
"Read Only" mode

1. Remove the test device from the foil pouch and place it on a flat and dry surface.
2. Use a 100 µℓ pipette to add 100 µℓ of mixed sample into the sample hole.

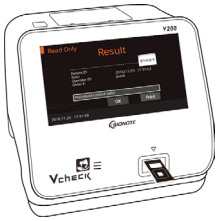


3. Leave the test device for 10 minutes. Note that the test device should not be left more than 13 minutes.

4. Turn on V200 Analyzer and select “Read Only” on the analyzer's screen.



5. Insert the test device to the V200 Analyzer.
6. The analyzer will automatically display the test result on the screen.
7. Remove the test device.



INTERPRETATION OF THE RESULT

[V200]

Negative

The negative result indicate the absence of FCoV antigen.

Positive

The positive result indicate the presence of FCoV antigen.

Invalid

The result might be considered invalid. The sample should be retested.

NOTE

Test results can be read by using test device only, but the results are unreliable. For more accuracy of test results, reading the results using V200 analyzer is recommended.

1. Only control("C") line in the result window indicate “Negative”.
2. Test("T") line and control("C") line within the result window indicate “Positive”.
3. If the control("C") line does not appear, the result might be considered invalid. The sample should be retested.

NOTE

The analyzer test result of a sample is given as Positive(+)/ Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. COI is calculated that a mesured signal is divided by an appropriate cutoff value.

- Test results of a COI≥ 1.00 are considered positive for FCoV Antigen.
- Test results of a COI< 1.00 are considered negative for FCoV Antigen.

LIMITATIONS OF THE TEST

1. Although the Vcheck FCoV Ag Test kit is very accurate in detecting Feline 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.
2. Neither the quantitative value nor the rate of FCoV Ag concentration can be determined by this qualitative test.
3. The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
4. BioNote and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

SCREEN MESSAGES AND TROUBLE SHOOTING

[V200]

Error message	Error description
Contaminated Device	The test device is damaged or inserted improperly. **Solution:** Discard the test device and retest with a new test device and a new specimen.
Insufficient Sample	An insufficient amount of blood has been applied. **Solution:** Retest with a new test device with enough specimen, ensuring that blood is placed in to the narrow channel in the top edge of the test device.
Expired Device	The test devices are expired. **Solution:** Retest with a new test device that is not expired.
Temperature Error	The environmental temperature is above or below the operating range of the analyzer. **Solution:** Move to an area in the acceptable temperature range for the analyzer and perform the test. Do not heat or cool the analyzer artificially.
Printer Connection Fail	The communication between analyzer and barcode or printer has failed. **Solution:** Reconnect the analyzer and external device. If the error continues after turning ON/OFF the analyzer, please contact BioNote, Inc.
Barcode Error	
Extremely High Total hemoglobin	The measured total hemoglobin is out of the range of 7 to 23 g/dL. **Solution:** This error occurs when a specimen has a total hemoglobin in the abnormal range. If the error continues after turning ON/OFF the analyzer, please contact BioNote, Inc.
Result: Invalid	The test is invalid. **Solution:** Retest with a new test device and a new patient specimen. If the error continues after turning ON/OFF the analyzer, please contact BioNote, Inc.
Calibration Overdue	The calibration is overdue. **Solution:** If the error continues after turning ON/OFF the analyzer, please contact BioNote, Inc.
Not Supported Device	A test device that is not supported by the analyzer has been loaded. **Solution:** Check whether the test device is manufactured by BioNote, Inc.
EEE	Internal error has occurred. **Solution:** If the error continues after turning ON/OFF the analyzer, please contact BioNote, Inc.

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