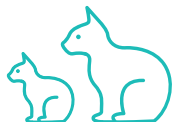


Vcheck

Feline SAA 3.0



FELINE SERUM AMYLOID A

For veterinary use only

INTENDED USE

The Vcheck Feline SAA 3.0 is an *in vitro* diagnostic test kit for the quantitative measurement of Serum Amyloid A (SAA) concentration in feline serum and plasma. SAA is one of the major acute-phase proteins and has low concentrations in healthy cats. As a sensitive marker of inflammation, its concentration increases in response to inflammatory stimuli such as infection, trauma, tumors, and surgery. Therefore, measurement of SAA concentration is useful to detect the presence of inflammation. Because SAA also reflects the recovery process, it may be used as a treatment response marker as well.

The BIONOTE Vcheck Feline SAA 3.0 is designed to be used only by veterinarians.

PRINCIPLE

The Vcheck Feline SAA 3.0 test kit is a fluorescent immunoassay for the quantitative measurement of Feline SAA concentration.

The Vcheck Feline SAA 3.0 test kit uses specific anti-Feline SAA antibodies that will bind to Feline SAA. The test procedure involves dissolving fluorescence microparticles conjugated to these specific antibodies into assay diluent that react with Feline SAA in the sample. When the specimen is applied to the sample hole of the test device, Feline SAA in the specimen migrates along the nitrocellulose membrane and forms complexes with the anti-Feline SAA antibodies coated on the membrane. As a result, the density of the test line reflects the concentration of Feline SAA in the serum or plasma. The BIONOTE Vcheck Analyzer reads the density of this test line and calculates the Feline SAA concentration from the calibration curve data. The control line is a reference line which indicates the test has been performed correctly.

MATERIALS PROVIDED

Reagent	5 Tests/Kit	10 Tests/Kit	20 Tests/Kit
① Vcheck Feline SAA 3.0 test device	5	10	20
② Assay diluent tube	5	10	20
③ Disposable pipette tip	10	20	40
④ Instructions for use	1	1	1

MATERIALS REQUIRED, BUT NOT PROVIDED

1. BIONOTE Vcheck Analyzer
2. 5 µl pipette
3. 100 µl pipette

STORAGE AND STABILITY

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

PRECAUTIONS

1. This test kit is for feline use only. Do not use for other animals.
2. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch.
3. Do not reuse the test components.
4. Do not touch the membrane in the result window of the test device.
5. Do not use the test kit beyond the stated expiry date marked on the label.
6. Do not use the test kit if the pouch is damaged or the seal is broken.
7. Do not mix components from different lot numbers; the components in this kit have been quality control tested as a standard batch unit.

8. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
9. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials safely in accordance with national and local regulations.
10. Do not use samples from patients with severe dehydration or shock conditions, or samples showing severe hyperlipidemia, hyperbilirubinemia, or hemolysis.
11. Strictly follow the test procedure including the amount of sample used, as failure to do so may adversely affect test performance and/or produce invalid results.
12. This reagent is designed for quantification of the SAA concentration in feline blood using a simple and quick method, but there may be differences in accuracy compared to other laboratory methods.
13. Final diagnosis must be confirmed by a veterinarian with other clinical data available.

COLLECTION AND PREPARATION OF SAMPLE

1. Feline serum or plasma should be used with this test.
2. **[Serum]** Collect the whole blood into a blood collection tube containing **NO** anticoagulant. Leave to settle for 30 minutes for blood coagulation and then centrifuge to obtain a serum supernatant.
[Plasma] Collect the whole blood into a blood collection tube containing anticoagulant (ONLY heparin). Then centrifuge to obtain plasma supernatant.
3. If serum or plasma samples are not tested immediately, they should be refrigerated at 2~8°C and used within 2 weeks. For longer storage, serum or plasma can be frozen (-20°C or colder). Frozen samples should be brought to room temperature (15~30°C) prior to use.

TEST PROCEDURE

Refrigerated reagents and samples must be at room temperature (15~30°C) before use.

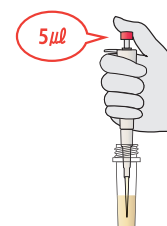
[Coding]

1. Turn on V200 Analyzer and select "Standard Test".
2. Remove the test device from the foil pouch. Once the "Insert Device" is displayed in the screen, insert the test device.
3. After checking Feline SAA item name and test procedure on the display window, proceed as follows.

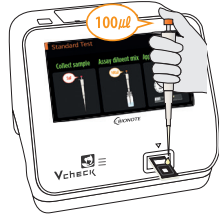


[Dilution of sample & Measurement]

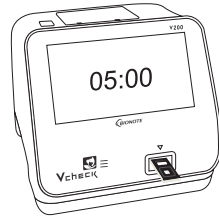
1. Using a 5 µl pipette, draw 5 µl of sample (serum or plasma) and add the sample into an assay diluent tube (0.5 mL).
2. Close the tube cap and shake for 5-6 times to mix the sample and the diluent thoroughly.



3. Add the mixed sample (100 µl) into the sample hole of the test device using a 100 µl pipette and press the "START" to initiate testing.



4. Read the concentration value appearing on the display after 5 minutes.
5. Remove the test device. The display then shows that BIONOTE Vcheck Analyzer is ready to test the next device.



INTERPRETATION OF THE RESULT

1. Read the concentration value of Feline SAA appearing on the display of the BIONOTE Vcheck Analyzer.
2. If "< 5 µg/ml" appears on the display, it means the concentration of Feline SAA in the specimen is less than 5 µg/ml.
3. If "> 200 µg/ml" appears on the display, it means the concentration of Feline SAA in the specimen is greater than 200 µg/ml.

REFERENCE RANGE

< 5 µg/ml	5~10 µg/ml	> 10 µg/ml
Normal	Equivocal	Abnormal

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.

PERFORMANCE CHARACTERISTIC

1. Measuring Range
5~200 µg/ml of Feline SAA is measurable in serum and plasma. For > 200 µg/ml results, samples may be diluted with negative sample and re-measured for a numerical result. To calculate the final Feline SAA concentration, the measured result must be multiplied by the dilution factor.
2. Interfering substances study
No interference was observed for each substance up to the concentration presented in the following table.

Interfering substances	Concentration
Hemoglobin	≤ 500 mg/dL
Intralipid	≤ 2,500 mg/dL
Cholesterol	≤ 1,000 mg/dL
Bilirubin (total)	≤ 15 mg/dL
Vitamin C	≤ 1,000 mg/L

3. Crossreactivity
There was no cross reactivity to similar molecules (CRP, Alpha 1-AG, Haptoglobin 300 µg/ml).

Doc. No. : IF138-2E
Issued date : May. 26, 2021