Vcheck

Equine SAA

EQUINE SERUM AMYLOID A

For veterinary use only

INTENDED USE

The Vcheck Equine SAA is an *in vitro* diagnostic test kit for the quantitative measurement of Serum Amyloid A (SAA) concentration in equine serum and plasma. SAA is one of the major acute-phase proteins and has low concentrations in healthy horses. As a sensitive marker of inflammation, its concentration increases in response to inflammatory stimuli such as infection, trauma, tumors, and surgery. Therefore, the measurement of SAA concentration is useful to detect the presence of inflammation. SAA can also be used as a treatment response marker because it reflects the recovery process. The BIONOTE Vcheck Equine SAA is designed to be used only by veterinarians.

PRINCIPLE

The Vcheck Equine SAA test kit is a fluorescent immunoassay for the quantitative measurement of Equine SAA concentration.
The Vcheck Equine SAA test kit uses specific anti-Equine SAA antibodies that will bind to Equine SAA. When the specimen is delivered to the sample hole of the test device, SAA in the specimen and the anti-Equine SAA antibody in a conjugated pad migrate along the nitrocellulose membrane. They react with the anti-Equine SAA antibody coated on the membrane. As a result, the density of the test line reflects the concentration of Equine SAA in the sample. The BIONOTE Vcheck Analyzer reads the density of this test line and calculates the Equine SAA concentration from the calibration curve data. The control line is a reference line that indicates the test has been performed correctly.

MATERIALS PROVIDED

Reagent	5 Tests/Kit	10 Tests/Kit	20 Tests/Kit
① Vcheck Equine SAA test device	5	10	20
② Assay diluent bottle	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 2~8 °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.

Reagent	Open status	Storage	Stability	Note
Test device	Unopened	2~8 °C, Sealed	12 months	Finished product
	Opened	Do not store	-	Use directly
Assay diluent	Unopened	2~8 °C, Sealed	12 months	Finished product
	Opened	Do not store	-	Use directly

PRECAUTIONS

1. This test kit is for equine use only. Do not use for other animals.
2. This reagent needs to be stored at 2~8 °C. If refrigerated, allow all kit components to reach room temperature (15~30 °C) prior to testing.
3. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the aluminum foil pouch.
4. Do not reuse the test components.
5. Do not touch the membrane in the result window of the test device.
6. Do not use the test kit beyond the stated expiry date marked on the 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; the components in this kit have been quality control tested as a 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, used kits, and potentially contaminated materials safely in accordance with national and local regulations.
11. Do not use samples from equines with severe dehydration or shock conditions, or samples showing severe hyperlipidemia, hyperbilirubinemia, or hemolysis.
12. Use plain serum tube only. Failure to do so may adversely affect test performance and/or produce invalid results.
13. Strictly follow the test procedure (e.g. adequate sample volume), as failure to do so may adversely affect test performance and/or produce invalid results.
14. This reagent is designed for quantification of the SAA concentration in equine blood using a simple and quick method, but there may be differences in accuracy compared to other laboratory methods.
15. Final diagnosis must be confirmed by a veterinarian with other clinical data available.
16. BIONOTE Vcheck Analyzer is recommended to use at 15~30 °C.

COLLECTION AND PREPARATION OF SAMPLE

1. Equine serum or plasma should be used with this test.
2. **[Serum]** Collect the whole blood into a blood collection tube containing NO anticoagulant (**ONLY** plain tube). Leave to settle for at least 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 samples are not tested immediately, they should be refrigerated at 2~8 °C and used within 7 days. For longer storage, samples can be frozen (-20 °C or colder) for two months. Frozen samples should be brought to room temperature (15~30 °C) prior to use.

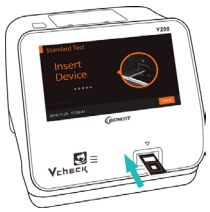
TEST PROCEDURE

* Allow all kit components and sample to reach room temperature (15~30 °C) prior to testing.
* Prepare the necessary kit components by referring to the 'MATERIALS PROVIDED' section.

[Coding]

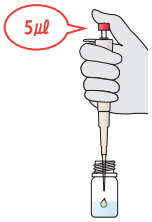
1. Turn on V200 Analyzer and select “Standard Test".

2. Remove the test device from the aluminum foil pouch. Once the “Insert Device” is displayed in the screen, insert the test device.
3. After checking Equine SAA item name and test procedure on the display window, proceed as follows.

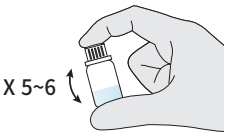


[Dilution of sample & Measurement]

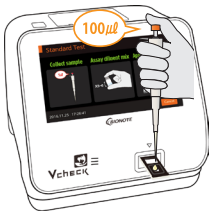
1. Use a 5 µℓ pipette to draw 5 µℓ of the sample (serum or plasma) and add the sample into an assay diluent bottle (2 mL).



2. Close the bottle 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.



*** Caution: If the time to press [START] button is delayed, it may affect the test result.**

4. The V200 Analyzer will display the test result on the screen after 5 minutes.

5. Remove the test device.

*** Strictly follow the test procedure including the amount of sample (5 µℓ) used and the test time (5 min), as failure to do so may adversely affect test performance and/or produce invalid results.**

INTERPRETATION OF THE RESULT

1. Read the concentration value of Equine SAA appearing on the display of the BIONOTE Vcheck Analyzer. (10~1,000 mg/L)
2. If "↓ 10 mg/L" appears on the display, it means the concentration of Equine SAA in the specimen is less than 10 mg/L.
3. If "↑ 1,000 mg/L" appears on the display, it means the concentration of Equine SAA in the specimen is greater than 1,000 mg/L.
4. If the [Invalid] result appears on the screen, a retest shall be carried out.

REFERENCE RANGE

< 10 mg/L	10~20 mg/L	> 20 mg/L
Normal	Equivocal	Abnormal (Inflammation)

* Each laboratory should establish its own reference interval, as reference values may vary depending on the test population.
* The veterinarian in charge must conduct a clinical diagnosis along with the measured results of this reagent, clinical symptoms, and other test results.

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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