

LifeAssays[®] Feline Serum Amyloid A test

E-25-0023-01

Intended Use

LifeAssays[®] Feline Serum Amyloid A (SAA) test Kit is an in vitro veterinary diagnostic system for quantitative determination of SAA in cat serum. It is intended to be used as an aid in the diagnosis, progression and treatment of various conditions associated with systemic inflammation. For professional use only.

Content Information

Reagent Vial (Art.no 40101-22/23).....	10/20 pcs
Algorithm Chip (Art.no.50501-10).....	1 pcs
Instructions for Use Leaflet (Art.no 40301-35).....	1 pcs
Liquid Control (50 µL, Art.no. 40201-11)	1 pcs

Material Required but Not Supplied with Kit

- LifeAssays[®] VetReader (Art.No. 50101-04)
- Vortex, e.g. LifeAssays[®] vortex (Art.No. 50201-04)
- Fixed volume 20 µL micro pipette (Art.No. 40301-34)

Stability and Storage

Store test kit and all components at 2–8° C. The test kit is stable until expiry date printed on the box. Avoid direct sunlight or exposure to temperatures above 25°C. Do not freeze.

Test Principle

LifeAssays[®] Feline SAA Test is a two-site heterogenous immunoassay. When the sample is placed into the reagent vial and the contents are mixed, polyclonal antibody coated silica microparticles, used as the solid phase in the assay, capture the Serum Amyloid A present in the sample. Antibody coated magnetic nanoparticles detect the Serum Amyloid A bound to the silica surfaces in a sandwich- binding format. The reagent vial is then loaded into the LifeAssays[®] VetReader and the instrument waits eleven minutes before measuring the test result. During these eleven minutes the silica microparticles sediment to the bottom of the reagent vial forming a solid phase pellet. The magnetic property of the solid phase pellet is measured quantitatively with the LifeAssays[®] VetReader by detecting the inductance change of the internal coil.

Each LifeAssays[®] Feline SAA Test Kit is delivered with one disposable algorithm chip. The chip contains all reagent data and a self-executable algorithm which will calculate the Serum Amyloid A test result in mg/L for the number of purchased tests. When the chip calculates a Serum Amyloid A result, it transfers the result back to the LifeAssays[®] VetReader for display.

Warnings and Precautions

- For *in vitro* veterinary diagnostic use only.
- Do not mix components from different kit containers.
- Do not use test kits after the expiry date.
- Do not use damaged or contaminated kits.
- Bring all test kit components to room temperature (18–25 °C) before use.
- The reagents contain sodium azide in concentrations <0.1% as a preservative. Sodium azide is a toxic agent. Avoid contact with skin and eyes. Flush abundantly with water upon disposal or if direct contact occurs.
- Wear disposable gloves while handling samples, kit reagents and wash hands thoroughly afterwards.
- Disposal of all specimen and test material should be in accordance with state and local law.

Specimen Collection and Preparation

LifeAssays[®] Feline SAA test can only be performed with serum samples.

Note: Repeated freezing and thawing of samples should be avoided. All samples must reach room temperature (18–25 °C) before testing. Frozen samples must be thawed completely, mixed thoroughly and brought to room temperature before testing is carried out.

Assay Procedure

Important Procedural Notes!

- Reagent vials and kit components must be allowed to reach room temperature (18–25 °C) before use.
- Reagent vials with reagent caught in the vial cap due to transport handling should be shaken (remove reagent from cap) and allowed to sediment for 15 minutes prior to use. To avoid loss of reagent never open a vial that has reagent caught in the cap.
- The procedure steps should be performed successively without any interruptions.
- Caps should be screwed on or closed tightly after use.
- For more information, see VetReader operator's manual.

1. Turn on Instrument

Insert the disposable algorithm chip provided with the LifeAssays[®] Feline SAA Test Kit and turn on the LifeAssays[®] VetReader. The Instrument performs a reagent chip control and displays, "wait 113" (with a numerical countdown from 113). The instrument will stabilize for about 10 minutes and display during this time, "Stab T".

2. Start-up

Remove a reagent vial from storage and allow it to reach room temperature. It is recommended to remove the reagent vial at least 15 minutes before a measurement is performed. Reagent vials with reagent caught in the vial cap due to transport handling should be shaken (remove reagent from cap) and allowed to sediment for 15 minutes prior to use. Never open a reagent vial that has reagent caught in the cap. This could lead to loss of reagent and erroneous results.

Follow the instructions given on the display of the VetReader. Once stabilization is complete, the instrument is ready for use and will display, "Fe SerumAA XX Tests" To start a measurement press and hold the enter button. The instrument will display, "wait" (3-second pause) followed by "Insert vial". Load a reagent vial into the VetReader. The instrument will display, "wait 5" and count down 5 seconds before displaying "Collect + Add Sample".

3. Add Sample

"Collect + Add Sample" will be displayed on the VetReader. Collect a 20 µL serum sample using a micropipette.

4. Add Sample

Unload the reagent vial from the VetReader. Open the cap of the reagent vial. Using a micropipette, add 20 µL of the serum sample and close the cap.

Note: The VetReader allows 5 seconds for adding sample before automatically switching to vortexing mode.

5. Mix using Vortex

"Vortex 30" will be displayed on the VetReader. Vortex the reagent vial for 30 seconds using the timer on display. Once the countdown has reached "0" the instrument will display, "Vortex OK".

Note: Make sure the pellet is completely suspended after vortexing by turning the reagent vial upside down.

6. Loading of Reagent Vial into Instrument

"Insert Vial 10" will be displayed on the VetReader with a numerical countdown from 10 seconds. Load the reagent vial back into the VetReader before the display shows "0". The instrument will display "Wait 660" and count down from 660 seconds (11 minutes). The user is now free to leave the instrument!

Note: The reagent vial must be loaded into the VetReader within 10 seconds after vortexing is completed. Otherwise, the measurement is aborted and the reagent chip will count down 1 measurement (the user loses one test).

7. Measurement

After 11 minutes the instrument will automatically perform 5 measurements, by moving the reagent vial in and out of the internal coil. The result is shown on the display in mg/L and will remain on the display until the reagent vial is unloaded from the instrument. The display on the instrument will show, “**Fe SerumAA XX mg/L**” where XX indicates a numerical value.

Note: *The user should never press or push the reagent vial back into the instrument during movement. Such an action could damage the mechanical moving parts of the instrument.*

8. Starting a New Measurement

Unload the reagent vial from the instrument. The display will show, “**Fe SerumAA Test XX**” where XX indicates the number of tests left of the reagent chip. To begin a new measurement press and hold the enter button. The instrument will display, “**wait**” (3-second pause) followed by “**Insert vial**”. Repeat the assay procedure from this point outlined in step 2.

Quality Control

The Feline SAA Liquid Control (Art. No. 40201-11) can be used to confirm the efficacy of the reagents and correct performance of the test. It is recommended to measure the control every time a new LifeAssays® Feline SAA Test Kit is opened. Routine measurement of the control allows for monitoring of values and trends. Test the control according to the procedure starting in section 2, in “Assay Procedure”.

Performance Characteristics

Linearity range

10–210 mg/L.

Correlation

Correlation factor 0.98 vs. ELISA SAA Phase (Tridelta Dev Ltd.).

Imprecision

Feline SAA (mg/L)	CV (%)
89	7

Reference Range

We recommend that results over 20 mg/L should be seen as an indication for systemic inflammation.

References

1. Céron J.J , Eckersall P.D.and Martinez-Subiela S. Vet. Clin. Pat. 2005, 34(2): 85–99. “Acute phase proteins in dogs and cats: current knowledge and future perspectives”.