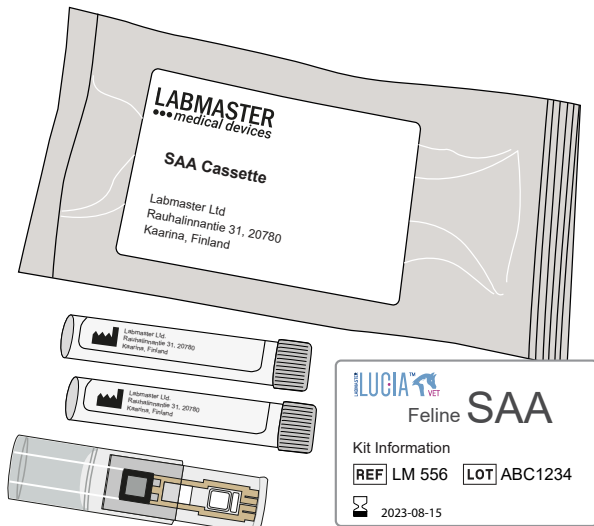




Instructions for Use

Labmaster LUCIA™ Feline SAA Kit
for Whole Blood Samples



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Labmaster LUCIA™ Feline SAA Kit for Whole Blood Samples

Product number: LM556

Product number: LM557

1. Intended Use

Labmaster LUCIA™ Feline SAA test is an *in vitro* veterinary diagnostic test for the quantitative determination of Serum Amyloid A (SAA) from cat whole blood to assess infection and inflammation status in cats. The Labmaster LUCIA™ Feline SAA Kit is intended to be used with semi-automated Labmaster LUCIA™ Vet Analyzer by veterinarians, laboratory professionals and animal attendants.

2. Clinical Significance and Summary of the Test

Feline Serum Amyloid A apolipoprotein (fSAA) is a significant acute phase infection marker in cats. The fSAA concentrations alter in response to a generalized inflammatory process (infections, immune-mediated illnesses, malignancy, and surgical intervention) (i). Scientific studies indicate that healthy cats have very low SAA levels, from 0 to 5 mg/L. fSAA can increase up to 100-fold from baseline levels within the first 8 to 24 hours of inflammatory stimuli (ii). Feline SAA is a helpful general marker of inflammation to track the progression of the condition and how well treatment is working. Since fSAA levels rapidly decline after the inflammation is reduced its levels are utilized to track early responses to antibiotic therapy and inform veterinarians when additional testing or treatment is required.

Measuring Range	Unit	Sample Volume	Sample Type	Measuring Time
5–200	mg/L	10 µL	Whole blood	6 minutes

3. Interpretation of Results

The reference range for a healthy cat is generally in the range of 0 to 5 mg/L. When interpreting the LUCIA Feline SAA test results, take into consideration the cat's medical history and other laboratory results.

4. Measuring Range

LUCIA Feline SAA test is used for measuring SAA with a range of 5–200 mg/L from whole blood sample. The sample is diluted before measurement. SAA < 5 mg/L is displayed if the Feline SAA concentration is below the measuring range. SAA > 200 mg/L is displayed if the Feline SAA concentration is above the measuring range.

LUCIA Feline SAA measurement from whole blood is based on the assumption that the volume of red blood cells is 40% of the total sample volume.

5. Kit Components

Contents of the Labmaster LUCIA™ Feline SAA Kit for Whole Blood Samples

Component Name	Product Number LM556 (10 Feline SAA tests)	Product Number LM557 (20 Feline SAA tests)
SAA Cassette*	10 pcs	20 pcs
Dilution Tube**	0.37 mL x 20 pcs	0.37 mL x 40 pcs
Feline SAA NFC Card	1 pc	1 pc
Feline SAA Instructions for Use and Quick Guide (see centrefold)	1 pc	1 pc

*Contains Tween, disodium tetraborate decahydrate, sodium azide, bovine serum albumin, bovine gamma globulin

**Contains Tween, bovine serum albumin, bovine gamma globulin, sodium azide

Materials Required but Not Provided with the Kit

Product Name	Product Number
Labmaster LUCIA™ Vet Analyzer	LM127
Labmaster LUCIA™ Vet Analyzer Instructions for Use	LM128
10 µL pipette and 10 µL filter tips*	N/A

*The 10 µL Single Volume Pipette (LM510) and 10 µL Filter tip rack (LM511) are available separately.

Storage

Store LUCIA Feline SAA Kit at +2 – +8 °C.

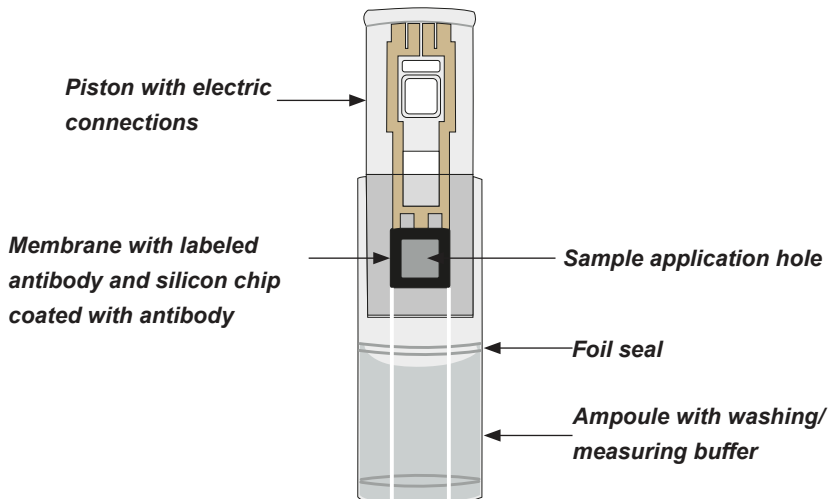


Figure 1. Labmaster LUCIA™ Feline SAA Cassette

6. Warnings and Precautions

Health and Safety Information

- For *in vitro* veterinary diagnostic use only.
- **Danger:** Washing/measuring buffer in cassette ampoule contains 1.7 mL of 1.9% disodium tetraborate decahydrate, which may damage fertility or the unborn child.



- Liquid reagents contain sodium azide < 0.1%, which is not considered a harmful amount.
- The kit should only be used by a veterinary healthcare professional or adequately trained personnel.
- Wear protective clothing and single use laboratory gloves when handling the veterinary samples or performing the test. Wash hands properly after performing the test.
- Avoid contact of liquids with eyes and skin. If exposed, rinse immediately with plenty of water.
- All veterinary samples and controls should be handled as potentially infectious material.
- Cassette packaging contains a desiccant. This material shall not be used in the assay. Discard the desiccant.
- Disposal: See section 12.

Analytical Precautions

- The Labmaster LUCIA™ Feline SAA Kit must be used only with the Labmaster LUCIA™ Vet Analyzer.
- Do not use kit components after the expiry date printed on the kit label.
- Do not mix components with other kit batches.
- NFC Card is batch specific and should be used only for Feline SAA tests from the same kit batch. If NFC Card is lost, a new card can be requested from support@labmaster.fi.
- Cassettes, dilution tubes and pipette tips are for single use. Do not use already used cassettes or dilution tubes.
- Measure diluted samples immediately after dilution.
- The Feline SAA Cassette should not be used if the cassette pouch is damaged or broken, if the foil seal in a cassette ampoule has broken and washing/measuring buffer has leaked from ampoule, or if there is crystal formation on the cassette. Please see section 13.
- Check that there are no air bubbles or foam in the cassette ampoule before use. If there are air bubbles, try to remove the bubbles by turning cassette upside down or tapping the ampoule gently. If the liquid in the ampoule has foamed, do not use the cassette.
- Use cassette immediately after cassette pouch has been opened.
- After the measurements, if there is a large air bubble which covers the whole surface of the silicon chip of the cassette or if the chip is covered by the foil seal, the measurement result is unreliable.

- Avoid contaminating the LUCIA Vet Analyzer.
- There is a possibility that other substances and/or factors may interfere with the test and cause erroneous results (e.g. technical or procedural errors).

7. Sample Material and Collection

Sample Material	Sample Volume	Sample Collection
Anticoagulated whole blood	10 μ L	Use venous blood sample collected in a tube containing lithium heparin or EDTA.* Mix whole blood by inverting the tube several times. Collect the sample using pipette, see section 9, Sample Dilution.

* If plasma or serum based samples are measured, result should be multiplied by factor 0.6.

8. Guide to Pipetting

The 10 μ L Single Volume Pipette (LM510)

1. Press the plunger to the first stop.
2. Insert the pipette tip into the liquid to a depth of approximately 1 cm and slowly release the plunger up. Withdraw the tip from the liquid.
3. Dispense the liquid by pressing the plunger to the first stop. After a delay of approximately one second, continue to press the plunger all the way to the second stop.
4. Withdraw the pipette tip from the liquid and release the plunger. DO NOT release the plunger while the tip is in the liquid. Change the pipette tip and continue pipetting.

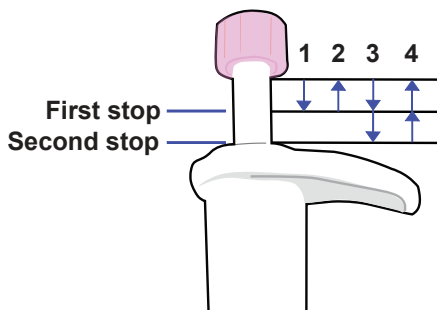


Figure 2. Pipette plunger

9. Procedure



NOTE: Kit components must be taken to room temperature 30 minutes prior to use.

NOTE: Each LUCIA Feline SAA Kit contains one batch specific NFC Card which is used for all tests in one kit. **Before measurement, ensure that NFC Card batch information corresponds to Feline SAA Cassette and Feline SAA Dilution Tube batch codes.**

The 10 μ L Fixed Volume Pipette (available separately) or any applicable 10 μ L pipette (not provided) can be used for sample transfer.

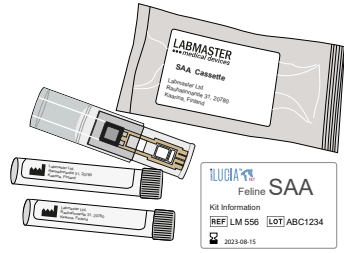
All dilution tubes in the kit are identical. **Take two Dilution Tubes and mark tubes clearly with numbers 1 and 2.**

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A Point-of-care platform based on patented CECL technology



Labmaster LUCIA™ Vet Analyzer



Components needed for one test:

- 1 cassette
- 2 dilution tubes
- 1 NFC Card (used for all tests in the kit)
- 10 µL pipette and 10 µL filter tips

Sample Dilution

Step 1

- Place a pipette tip onto the 10 µL pipette.
- Press the plunger down to the first stopper.

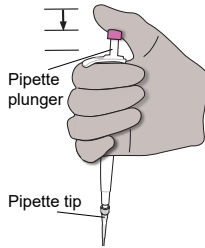


Figure: Step 1

Step 2

- Pipette 10 µL of the blood sample.

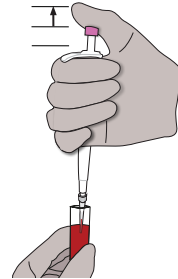


Figure: Step 2

Step 3

- Dispense the sample into the buffer in dilution tube 1. Make sure the pipette tip is completely empty.
- Close the cap of dilution tube 1 and turn the tube sharply upside down at least 5 times. Do not shake the tube.

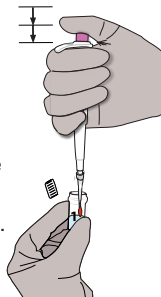


Figure: Step 3

Step 4

- With a new pipette tip, pipette 10 µL of diluted sample from tube 1.

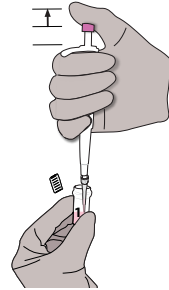


Figure: Step 4

Step 5

- Dispense the sample into the buffer in tube 2 (see quick guide, step 4).
- Close the cap of tube 2 and turn the tube sharply upside down at least 5 times. Do not shake tube 2.
- The diluted sample is now ready to be measured.
- The diluted sample must be measured immediately.

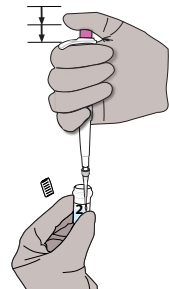


Figure: Step 5

Measurement

Step 6

- Open the pouch containing the SAA Cassette and check that there are no small air bubbles or foam in the cassette ampoule before sample application. If there are small air bubbles, try to remove them by turning the cassette upside down or tapping the ampoule gently. If the liquid in the ampoule has foamed, do not use the cassette. After cassette ampoule has been checked, use the cassette immediately.
- Select the veterinary patient sample measurement icon on LUCIA Analyzer's display, enter veterinary patient ID and read the NFC card as instructed in the Labmaster LUCIA™ Instructions for Use. **NOTE: the diluted sample has to be dispensed into the cassette during the 1-minute time window after the NFC Card has been read.**

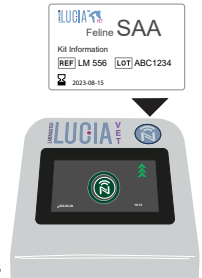


Figure: Step 6

Step 7

- Slide the cassette onto the tray of the analyzer from the right side of the tray.

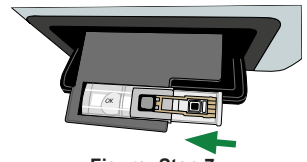


Figure: Step 7

Step 8

- Using a new pipette tip, collect 10 µL of diluted sample from dilution tube.

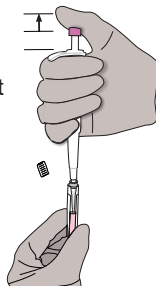


Figure: Step 8

Step 9

- Dispense the sample to the cassette without touching the membrane. Do not release the plunger.
- Keep the plunger down and touch the membrane with the pipette tip. Hold the pipette tip against the membrane until the sample has spread on the entire membrane.
- Make sure that the pipette tip is completely empty. If the tip is not completely empty, the test result is not reliable.

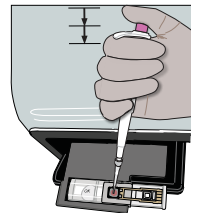


Figure: Step 9

Step 10

- Immediately after adding the sample, start the measurement by selecting the Accept icon on the display.



Figure: Step 10

Step 11

- The result will be shown on the analyzer's display and the door opens and the tray comes out.
- Check that the silicon chip is not covered by large air bubble or by foil.
- Remove cassette from the tray.
- Dispose of the cassette immediately after use.
- Place the NFC Card back into the kit box.

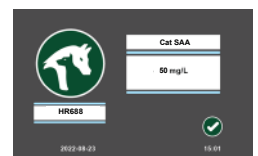


Figure: Step 11



See the Labmaster LUCIA™ Vet Analyzer's Instructions for Use for more detailed measurement instructions.

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10. Quality Control

Both the Labmaster LUCIA™ Vet Analyzer and LUCIA Feline SAA test are factory calibrated. The use of control material is advised to assure the day-to-day validity of results. User can use a commercial Feline SAA control or prepare and measure own quality control.

Commercial controls should be handled according to the Instructions for Use provided with the controls. The user sets the limit values for the controls.



See the Labmaster LUCIA™ Vet Analyzer's Instructions for Use for more detailed measurement instructions.

11. Limitations of the Procedure

Follow the sample collection, dilution and assay procedures specified in these instructions, otherwise the results might not be reliable. Test results should never be used alone for making a diagnosis.

12. Disposal

All samples and materials shall be disposed of according to local law and regulations. All samples, used cassettes, dilution tubes and pipette tips shall be disposed of as biological, potentially infectious materials. Paper, carton and pouches from LUCIA Feline SAA Kit can be recycled according local and national instructions. Desiccants and NFC Card can be disposed of in general waste. This product will not cause any health risk if used in accordance with the Instructions for Use.

13. Troubleshooting











For Analyzer-related questions see Labmaster LUCIA™ Vet Analyzer (LM127) Instructions for Use (LM128).

Symptom	Probable Causes	Corrective Action
<ul style="list-style-type: none"> Washing/measuring buffer has leaked from ampoule or there is crystal formation on the cassette. 	<ul style="list-style-type: none"> Foil seal in the cassette ampoule has broken. 	<ul style="list-style-type: none"> Do not use the cassette. If the problem reoccurs, contact support@labmaster.fi.
<ul style="list-style-type: none"> Washing/measuring buffer inside the cassette has foamed. 	<ul style="list-style-type: none"> Cassette has been handled heavy-handedly or cassette has been dropped. 	<ul style="list-style-type: none"> Do not use the cassette. If the problem reoccurs, contact support@labmaster.fi.
<ul style="list-style-type: none"> Sample does not go through membrane. 	<ul style="list-style-type: none"> Kit has not been stored at the instructed storage temperature or the cassette pouch has broken. Cassette has been taken out of the pouch too early. 	<ul style="list-style-type: none"> Do not use the cassette. If the problem reoccurs, contact support@labmaster.fi.
<ul style="list-style-type: none"> Liquid residue on the tray. 	<ul style="list-style-type: none"> Washing/measuring buffer has leaked from ampoule. 	<ul style="list-style-type: none"> Blot the liquid into a soft paper or cloth. If the problem reoccurs, contact support@labmaster.fi.
<ul style="list-style-type: none"> Rejected measurement. 	<ul style="list-style-type: none"> Air bubble or foil seal on top of silicon chip. Air bubbles or foam in washing/measuring buffer. 	<ul style="list-style-type: none"> Repeat the measurement using a new cassette. If the problem reoccurs, contact support@labmaster.fi.
<ul style="list-style-type: none"> Grinding sound during tray movement. 	<ul style="list-style-type: none"> Mechanical malfunction. Cassette is placed on the tray incorrectly. 	<ul style="list-style-type: none"> Restart the LUCIA Vet Analyzer. Repeat the measurement using a new cassette. If the problem reoccurs, contact support@labmaster.fi.
<ul style="list-style-type: none"> Foil seal covers the silicon chip after measurement. 	<ul style="list-style-type: none"> Defective cassette. 	<ul style="list-style-type: none"> Measurement result is unreliable, do not use the result. Repeat the measurement using a new cassette. If the problem reoccurs, contact support@labmaster.fi.

14. References

- i. Eckersall, P. D., & Bell, R. (2010). Acute phase proteins: Biomarkers of infection and inflammation in veterinary medicine. *The veterinary journal*, 185(1), 23-27. <https://doi.org/10.1016/j.tvjl.2010.04.009>.
- ii. Tamamoto, T., Ohno, K., Ohmi, A., Goto-Koshino, Y., & Tsujimoto, H. (2008). Verification of measurement of the feline serum amyloid A (SAA) concentration by human SAA turbidimetric immunoassay and its clinical application. *The Journal of veterinary medical science*, 70(11), 1247–1252. <https://doi.org/10.1292/jvms.70.1247>.

15. Explanation of Symbols

Symbol	Description
	Manufacturer
	Use by date (YYYY-MM-DD)
	Temperature limit
	Do not reuse
	Consult Instructions for Use
	Catalog number
	Batch code
	Contents sufficient for <n> Tests
	Caution
	Serious health hazard

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