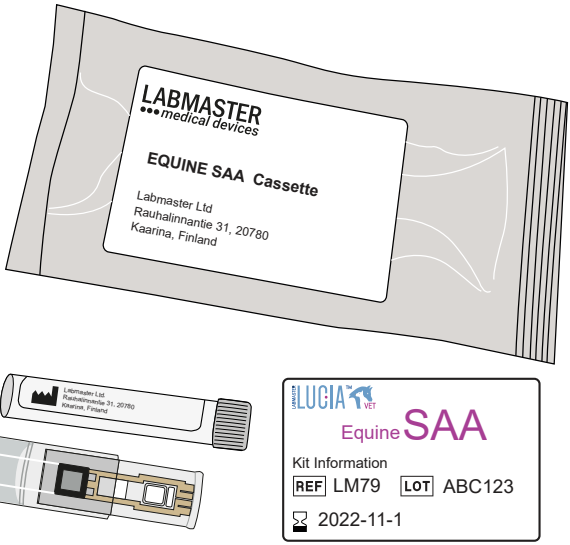
Instructions for Use

Labmaster LUCIA™ Equine SAA Kit
for Whole Blood Samples



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medical devices

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Labmaster LUCIA™ Equine SAA Kit for Whole Blood Samples

Product number: LM435 (10 tests)
Product number: LM546 (20 tests)
Product number: LM79: (40 tests)

1. Intended Use

Labmaster LUCIA™ Equine SAA test is an *in vitro* veterinary diagnostic test for the quantitative determination of Equine Serum Amyloid A (SAA) from whole blood to assess infection and inflammation status in horses. The Labmaster LUCIA™ Equine SAA Kit is 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

Serum amyloid A (SAA) is an equine acute phase response protein. SAA concentration rises in response to inflammation and has been shown to be an effective inflammatory marker in horses. Circulating SAA concentrations may increase up to 1000-fold following inflammation, infection or tissue injury. (i–iii)

Measuring Range	Unit	Sample Volume	Sample Type	Measuring Time
10–1500	mg/L	10 µL	Whole blood	6 minutes

3. Interpretation of Results

The reference range for a healthy horse is generally in the range of <0.5 to 20 mg/L (i, iv). When interpreting the LUCIA Equine SAA test results, take into consideration the horse's medical history and other laboratory results.

4. Measuring Range

LUCIA Equine SAA test is used for measuring SAA with a range of 10–1500 mg/L from whole blood sample. The sample is diluted before measurement. SAA < 10 mg/L is displayed if the Equine SAA concentration is below the measuring range. SAA > 1500 mg/L is displayed if the Equine SAA concentration is above the measuring range.

LUCIA Equine 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™ Equine SAA Kit for Whole Blood Samples

Component Name	Product Number LM435 (10 Equine SAA tests)	Product Number LM546 (20 Equine SAA tests)	Product Number LM79 (40 Equine SAA tests)
SAA Cassette*	10 pcs	20 pcs	40 pcs
SAA Dilution tube for Whole Blood sample **	6.0 mL x 10 pcs	6.0 mL x 20 pcs	6.0 mL x 40 pcs
Equine SAA NFC Card	1 pc	1 pc	1 pc
SAA Instructions for Use and Quick Guide (see centrefold)	1 pc	1 pc	1 pc

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

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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 Equine SAA Kit at +2 – +8 °C.

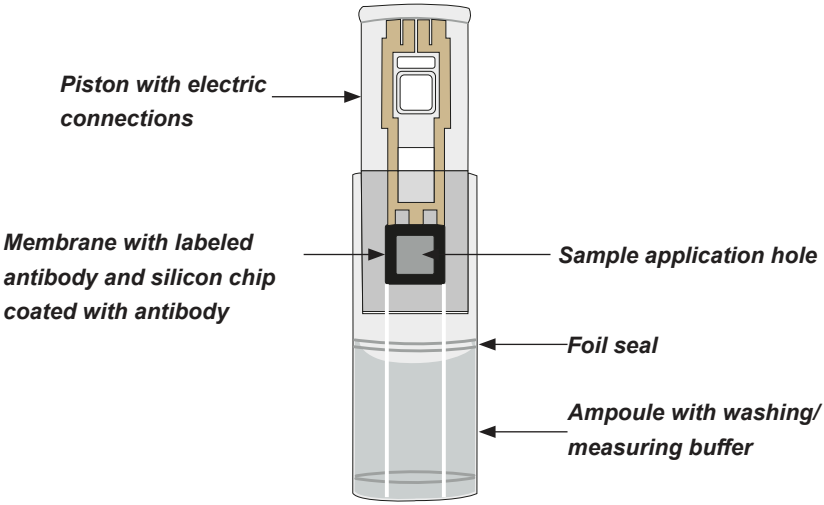

Figure 1. Labmaster LUCIA™ SAA Cassette

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™ Equine 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 Equine 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, dilution tubes or pipette tips.
- The 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 them 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.
- Do not use components of LUCIA Equine SAA Kit if they have not been stored as instructed in this kit insert.

- 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 µL	Use venous blood sample collected in a tube containing EDTA or heparin*. 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 µL 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.

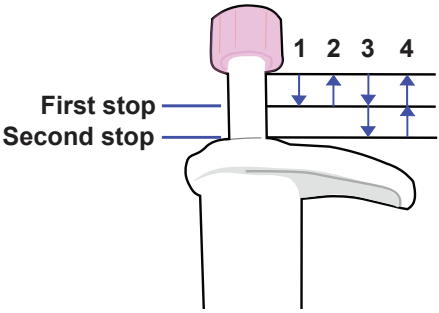

Figure 2. Pipette plunger

9. Procedure

NOTE: Immediately use the kit components taken to room temperature.

NOTE: Each LUCIA Equine 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 SAA Cassette and SAA Dilution tube batch codes.**

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

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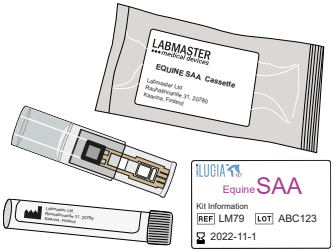
LUCIA™ VET

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

Labmaster LUCIA™ Vet Analyzer



Components needed for one test:
- ***1 cassette***
- ***1 dilution tube***
- ***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.

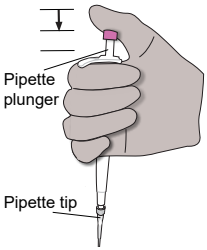


Figure: Step 1

Step 2

- Pipette 10 µl of the blood sample.

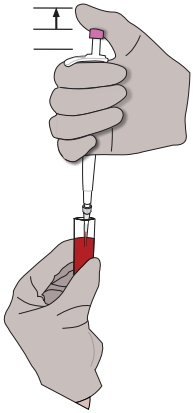


Figure: Step 2

Step 3

- Dispense the sample into the buffer in dilution tube. Make sure the pipette tip is completely empty.
- Close the cap of dilution tube and turn the tube upside down at least 5 times. Do not shake the tube.
- The diluted sample is now ready to be measured.
- The diluted sample must be measured immediately.

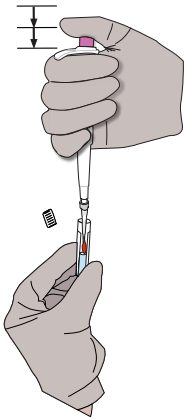


Figure: Step 3

Measurement

Step 4

- Open the pouch containing the Equine 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.**

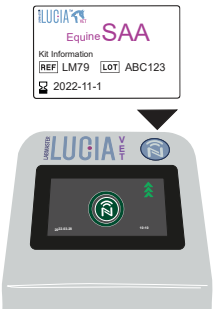


Figure: Step 4

Step 5

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

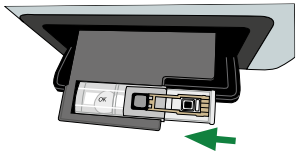


Figure: Step 5

Step 6

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

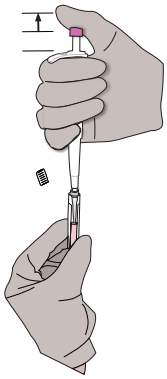


Figure: Step 6

Step 7

- 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.

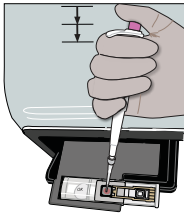


Figure: Step 7

Step 8

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

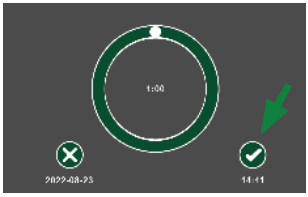


Figure: Step 8

Step 9

- The result will be shown on the analyzer's display and the door opens and 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.

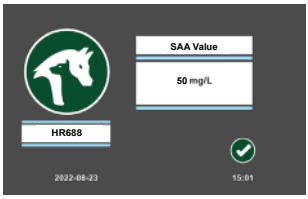


Figure: Step 9

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 Equine 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 equine SAA control or prepare and measure own quality control.

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 Equine 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
• Washing/measuring buffer has leaked from ampoule or there is crystal formation on the cassette.	• Foil seal in the cassette ampoule has broken.	• Do not use the cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Washing/measuring buffer inside the cassette has foamed.	• Cassette has been handled heavy-handedly or cassette has been dropped.	• Do not use the cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Sample does not go through membrane.	• 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.	• Do not use the cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Liquid residue on the tray.	• Washing/measuring buffer has leaked from ampoule.	• Blot the liquid into a soft paper or cloth. • If the problem reoccurs, contact support@labmaster.fi.
• Rejected measurement.	• Air bubble or foil seal on top of silicon chip. • Air bubbles or foam in washing/measuring buffer.	• Repeat the measurement using a new SAA Cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Grinding sound during tray movement.	• Mechanical malfunction. • Cassette is placed on the tray incorrectly.	• Restart the LUCIA Vet Analyzer. • Repeat the measurement using a new SAA Cassette. • If the problem reoccurs, contact support@labmaster.fi.
• Foil seal covers the silicon chip after measurement.	• Defective cassette.	• Measurement result is unreliable, do not use the result. • Repeat the measurement using a new SAA Cassette. • If the problem reoccurs, contact support@labmaster.fi.

14. References

i. Witkowska-Piłaszewicz O.D., Żmigrodzka M., Winnicka A., Miśkiewicz A., Strzelec K., Cywińska A. (2019). Serum amyloid A in equine health and disease. Equine Veterinary Journal 51: 293-298.

ii. Jacobsen S., Andersen P.H. The acute phase protein serum amyloid A (SAA) as marker of inflammation in horses (2007). Equine Veterinary Education 19: 38-46.

iii. Nunokawa Y., Fujinaga T., Taira T., Okumura M., Yamashita K., Tsunoda N., Hagio M. (1993). Evaluation of serum amyloid A as an acute-phase reactive protein in horses. Journal Veterinary Medical Science 55: 1011-1016.

iv. Rossdales Laboratories. [online]. https://www.rossdales.com/laboratories/tests-and-diseases/serum-amyloid-a-saa.

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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Title: C80 Equine SAA Kit for Whole Blood Samples LM79 LM435 LM546 EN

Approved version: 3

Document: LM-001024-LA

Reviewed and approved by:

Quality manager - Satu Tiittanen Thu 17.08.2023

Approved and signed `Mv9lS4B+BY3LGeBqJFmDjIetLYo`

Approval History:

Version	Approved on	Status	Issued by
3	Thu 17.08.2023	Approved	Satu Tiittanen
Version	**Approved on**	**Status**	**Issued by**