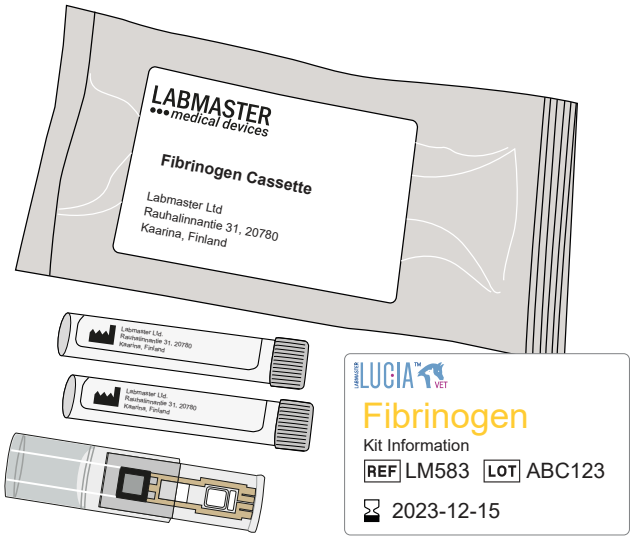
Instructions for Use

Labmaster LUCIA™ Fibrinogen Kit



LABMASTER
medical devices

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Labmaster LUCIA™ Fibrinogen Kit

Product number: LM583 10 tests
Product number: LM584 20 tests

1. Intended Use

Labmaster LUCIA™ Fibrinogen test is an *in vitro* veterinary diagnostic test for the quantitative determination of Fibrinogen from horse whole blood and plasma to assess infection and inflammation status in horses. The Labmaster LUCIA™ Fibrinogen 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

Fibrinogen is a large protein that plays a crucial role in the blood clotting process. Fibrinogen is converted to fibrin, forming a meshwork that traps blood cells and helps stop the bleeding. Fibrinogen can also be used as a diagnostic tool. Elevated equine fibrinogen levels are often indicative of inflammation and tissue damage (i). When measured serially with Equine Fibrinogen the kinetics of the inflammatory response can often be determined and this can be very helpful when monitoring response to treatment (ii).

Measuring Range	Unit	Sample Volume	Sample Type	Measuring Time
100-1700	mg/dL	10 µL	Whole blood, Plasma	6 minutes

3. Interpretation of Results

The reference range for a healthy horse is generally 2–4 g/L (200–400 mg/dL) (i). When interpreting the LUCIA Fibrinogen test results, take into consideration the horse's medical history and other laboratory results.

4. Measuring Range

LUCIA Fibrinogen test is used for measuring fibrinogen with a range of 100–1700 mg/dL from anticoagulated[1] whole blood samples or plasma. The sample is diluted before measurement. Fibrinogen < 100 mg/dL is displayed if the Fibrinogen concentration is below the measuring range. Fibrinogen > 1700 mg/dL is displayed if the Equine Fibrinogen concentration is above the measuring range.

1 Na-citrate

5. Kit Components

Contents of the Labmaster LUCIA™ Fibrinogen Kit

Component Name	Product Number LM583 (10 Fibrinogen tests)	Product Number LM584 (20 Fibrinogen tests)
Fibrinogen Cassette*	10 pcs	20 pcs
Dilution Tube**	0.80 mL x 20 pcs	0.80 mL x 40 pcs
LUCIA Fibrinogen NFC Card	1 pc	1 pc
LUCIA Fibrinogen Instructions for Use and Quick Guide (see centrefold)	1 pc	1 pc

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

***Contains Bovine serum albumin, 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 Fibrinogen Kit at +2 – +8 °C.

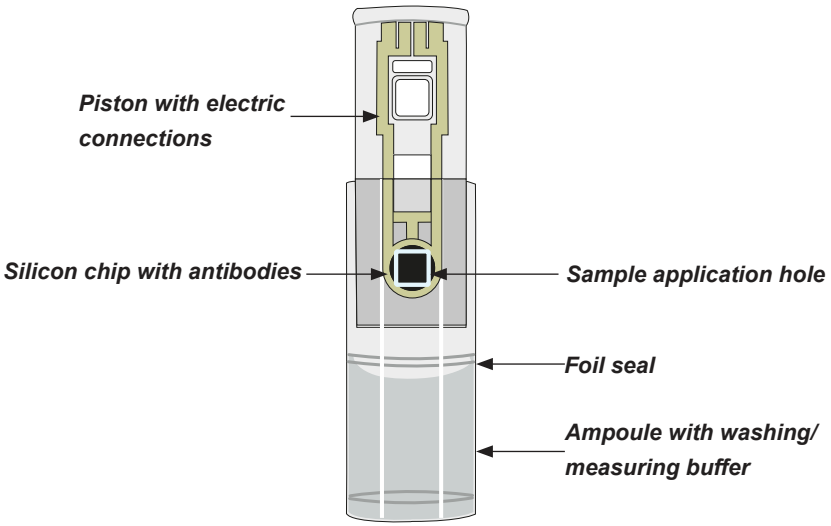

Figure 1. Labmaster LUCIA™ Fibrinogen Cassette

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™ Fibrinogen 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 Fibrinogen 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 Fibrinogen 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.
- There is a large air bubble in the cassette ampoule. If in addition there are small 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 µL	Use venous blood sample collected in a tube containing Na-Citrate. Mix whole blood by inverting the tube several times.
Anticoagulated plasma	10 µL	Use plasma separated from Na-Citrate tube. If plasma 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.

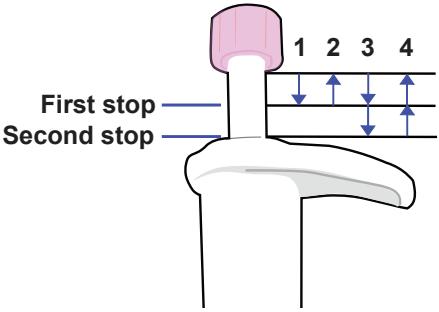

Figure 2. Pipette plunger

9. Procedure

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

NOTE: Each LUCIA Fibrinogen 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 Fibrinogen Cassette and Fibrinogen Dilution Tube batch codes.**

The 10 µL Fixed Volume Pipette (available separately) or any applicable 10 µL 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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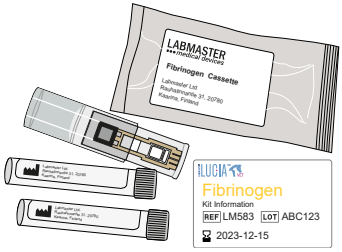
LUCIA™ VET

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.

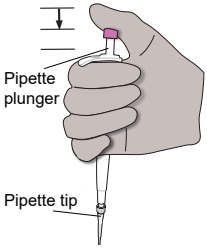


Figure: Step 1

Step 2

- Pipette 10 µL of the blood sample.

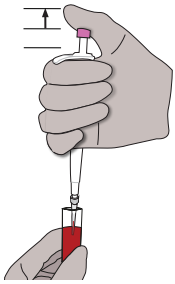


Figure: Step 2

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 dilution tube.

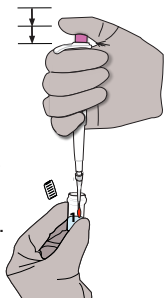


Figure: Step 3

Step 4

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

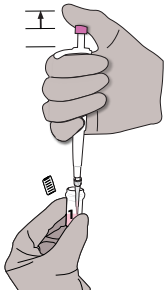


Figure: Step 4

Step 5

- Dispense the sample into the buffer in dilution tube 2
- Close the cap of dilution tube 2 and turn the tube sharply upside down at least 5 times. Do not shake dilution tube 2.
- The diluted sample is now ready to be measured.
- The diluted sample must be measured immediately.

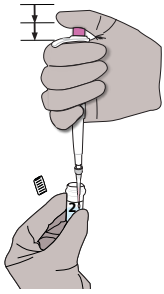


Figure: Step 5

Measurement

Step 6

- Open the pouch containing the Fibrinogen Cassette and check the cassette 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.**

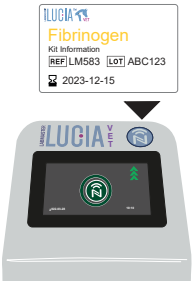


Figure: Step 6

Step 7

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

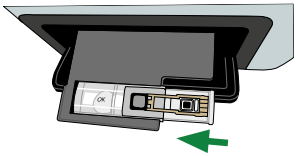


Figure: Step 7

Step 8

- Using a new pipette tip, collect 10 µL of diluted sample from dilution tube 2.

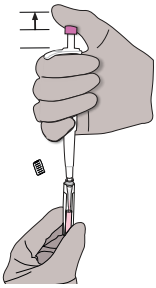


Figure: Step 8

Step 9

- Dispense the sample to the cassette.

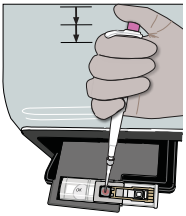


Figure: Step 9

Step 10

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

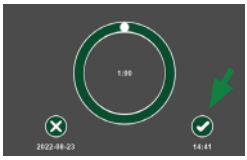


Figure: Step 10

Step 11

- After the measurement is completed, the result will be shown on the analyzer's display and the door opens and the tray comes out.
- If plasma sample was used, multiply the result by factor 0.6.
- 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.

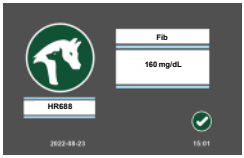


Figure: Step 11

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 Fibrinogen 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 fibrinogen 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 Fibrinogen Kit can be recycled according to 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.
• 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 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 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 cassette. • If the problem reoccurs, contact support@labmaster.fi.

14. References

i. Jacobsen S. Review of equine acute-phase proteins. P Annu Conv Am Equin. (2007) 53:230–5.

ii. Thurston, C. C., Stefanovski, D., MacKinnon, M. C., Chapman, H. S., Richardson, D. W., & Levine, D. G. (2022). Serum amyloid A and fibrinogen as markers for early detection of surgical site infection associated with internal fixation in the horse. Frontiers in veterinary science, 9, 960865. https://doi.org/10.3389/fvets.2022.960865.

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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Reviewed and approved by:

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Regulatory director - Kirsi-Marja Meri Mon 05.02.2024

Reviewed and signed `9WZVF4TFWuwIezWNV7GhDhB27Wk`

Quality manager - Satu Tiittanen Tue 13.02.2024

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Approval History:

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2	Tue 13.02.2024	Approved	Niina Moilanen
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