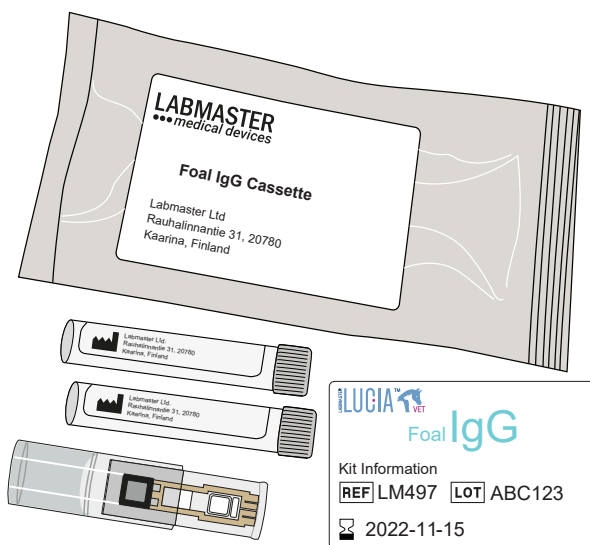




Instructions for Use

Labmaster LUCIA™ Foal IgG Kit
for Whole Blood Samples



LABMASTER
•••medical devices

Labmaster LUCIA™ Foal IgG Kit for Whole Blood Samples

Product number: LM431

Product number: LM497

1. Intended Use

Labmaster LUCIA™ Foal IgG test is an *in vitro* veterinary diagnostic test for the quantitative determination of Immunoglobulin G (IgG) from foal whole blood to assess failure of transfer of passive immunity (FTPI). The Labmaster LUCIA™ Foal IgG Kit is intended to be used with semi- automated Labmaster LUCIA™ Vet Analyzer by veterinarians, laboratory professionals and animal attendants. The Labmaster LUCIA™ Foal IgG Kit is intended to be used at different environments: veterinarians' offices, laboratories and stables.

2. Clinical Significance and Summary of the Test

Foals with failure of transfer of passive immunity (FTPI)(<400 mg/dL) are at increased risk of infections and death. Immunoglobulin G (IgG) concentrations of 400–800 mg/dL may be considered partial failure of passive immunity. Although IgG concentration of >800 mg/dL is already considered adequate, many foals have IgG concentrations that are much higher (i).

Measuring Range	Unit	Sample Volume	Sample Type	Measuring Time
100–2500	mg/dL	10 µL	Whole blood	6 minutes

3. Measuring Range

LUCIA Foal IgG test is used for measuring IgG with a range of 100–2500 mg/dL from anticoagulated whole blood samples or serum/plasma. The sample is diluted before measurement. Foal IgG < 100 mg/dL is displayed if the Foal IgG concentration is below the measuring range. Foal IgG > 2500 mg/dL is displayed if the Foal IgG concentration is above the measuring range.

4. Interpretation of Results

Serum immunoglobulin G (IgG) concentrations	Interpretation (i)
< 400 mg/dL	Failure of immune transfer
400 – 800 mg/dL	Partial failure of immune transfer
> 800 mg/dL	Adequate

5. Kit Components

Contents of the Labmaster LUCIA™ Foal IgG Kit for Whole Blood Samples

Component Name	Product Number LM431 (10 Foal IgG tests)	Product Number LM497 (20 Foal IgG tests)
Foal IgG LUCIA Cassette*	10 pcs	20 pcs
Foal IgG Dilution Tube**	0.99 mL x 20 pcs	0.99 mL x 40 pcs
Foal IgG NFC Card	1 pc	1 pc
Foal IgG Instructions for Use and Quick Guide (see centrefold)	1 pc	1 pc

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

**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 Foal IgG Kit at +2 – +8 °C.

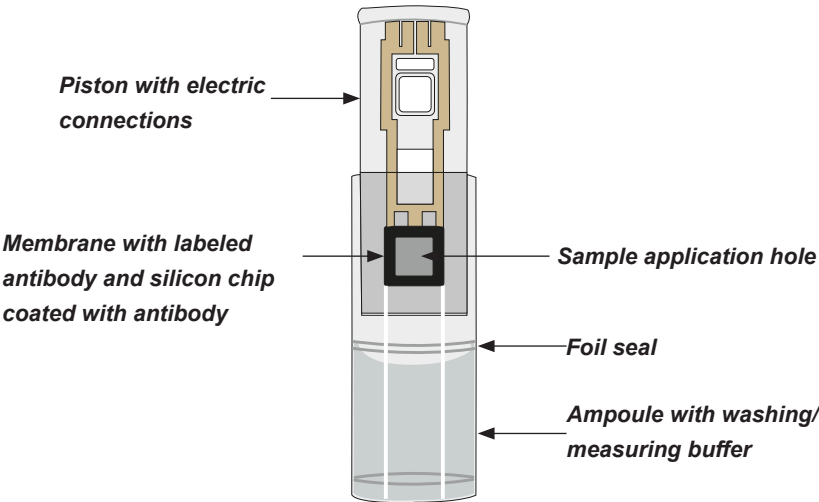


Figure 1. Labmaster LUCIA™ Foal IgG Cassette

6. Warnings and Precautions

Health and Safety Information

- For *in vitro* veterinary diagnostic use only.
- 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.
- Liquid reagents contain sodium azide < 0.1%, which is not considered a harmful amount.
- **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.



- Cassette packaging contains a desiccant. This material shall not be used in the assay. Discard the desiccant.
- Disposal: See section 13.

Analytical Precautions

- The Labmaster LUCIA™ Foal IgG 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 Foal IgG tests from the same kit batch. If NFC Card is lost, a new card can be requested from support@labmaster.fi.
- Cassettes and dilution tubes are for single use. Do not use already used cassettes or dilution tubes.
- Measure diluted samples immediately after dilution.
- The Foal IgG 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 14.
- 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.
- Do not use components of LUCIA Foal IgG 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 lithium heparin or EDTA. Mix whole blood by inverting the tube several times. Collect the sample using pipette, see section 8, Sample Dilution.
Anticoagulated serum/plasma	10 µL	Use serum/plasma separated from lithium heparin or EDTA. If serum/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.

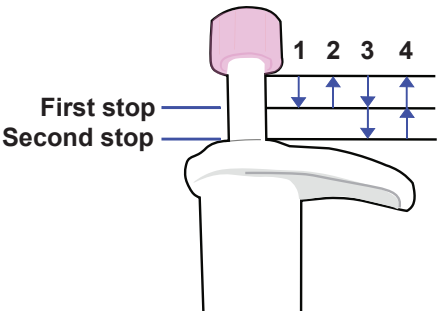



Figure 2. Pipette plunger

9. Procedure



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

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

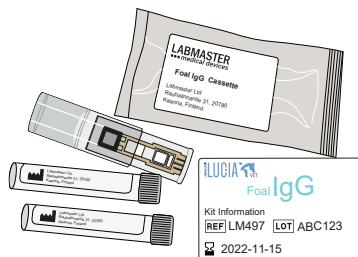
The 10 µl Fixed Volume Pipette (available separately) or any applicable 10 µl pipette (not provided) can be used for sample transfer.

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

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 μ L pipette and 10 μ L filter tips

Sample Dilution

Step 1

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

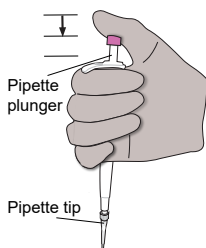


Figure: Step 1

Step 2

- Pipette 10 μ L of the blood sample.

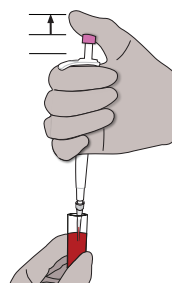


Figure: Step 2

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.

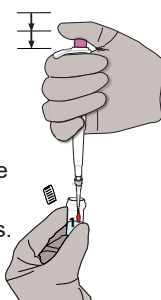


Figure: Step 3

Step 4

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

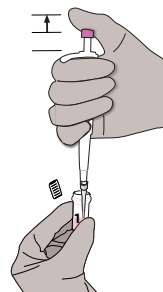


Figure: Step 4

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.

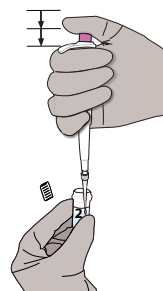


Figure: Step 5

Measurement

Step 6

- Open the pouch containing the Foal IgG 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.**

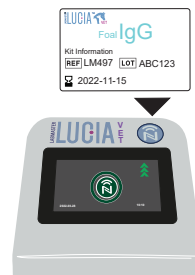


Figure: Step 6

Step 7

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

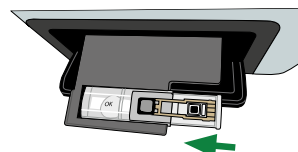


Figure: Step 7

Step 8

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

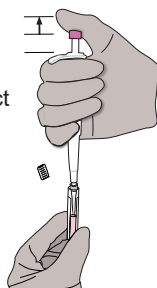


Figure: Step 8

Step 9

- Dispense the sample to the cassette.

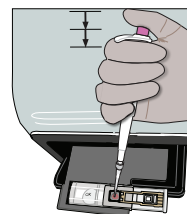


Figure: Step 9

Step 10

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

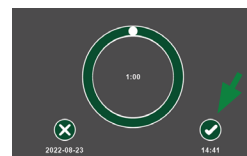


Figure: Step 10

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 serum/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.

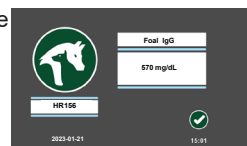


Figure: Step 11



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

10. Quality Control

Both the Labmaster LUCIA™ Vet Analyzer and LUCIA Foal IgG 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 Foal IgG 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.

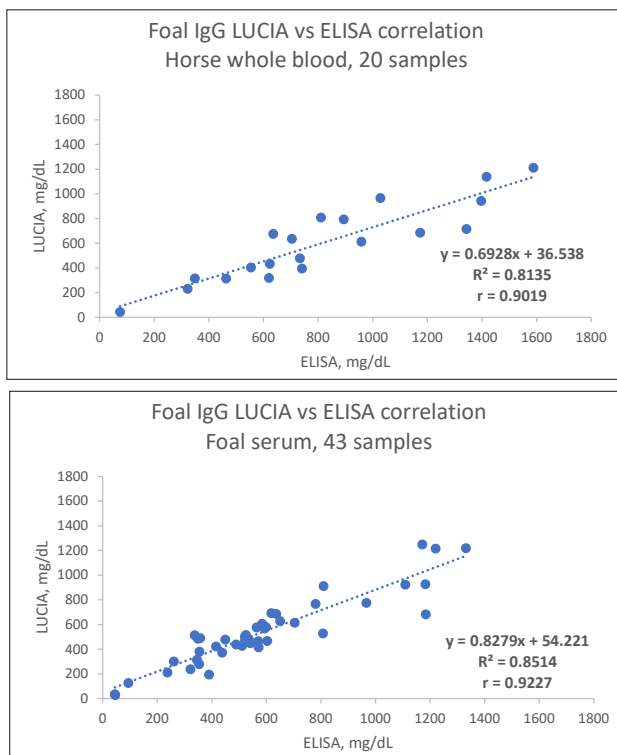
11. Limitations of the Procedure

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. Performance Characteristics

Method Comparison

Method comparison for the Labmaster LUCIA Foal IgG test kit was done by comparing to Equine IgG ELISA kit from BioPanda. 20 horse whole blood samples and 43 foal serum samples, both covering the majority of the LUCIA Foal IgG Kit measuring range of 100-1500 mg/dL were measured with both assays. Good correlation was obtained with both matrices.



Precision

Precision was determined by applying CLSI guideline EP05-A3 (ii) using 2 levels of horse whole blood. The whole blood samples were measured as 50 replicates during 1 day using 2 operators, 5 analyzers, 2 cassette lots per analyzer, single run per cassette lot at each analyzer and 5 replicates per run.

Sample level	Mean concentration, mg/dL	N	Repeatability (within-run)		Within-Laboratory	
			SD	CV%	SD	CV%
Low	526	50	87	16	108	20
High	753	50	159	21	212	28

Analytical sensitivity

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) on whole blood were determined by applying CLSI guideline EP17-A2. (iii)

Description	Result (mg/dL)
Limit of Blank (LoB)*	31
Limit of Detection (LoD)**	43
Limit of Quantitation (LoQ)***	43

* Limit of Blank (LoB) is the highest measurement that is likely to be observed for a blank sample.

** Limit of Detection (LoD) is the lowest concentration that can be differentiated from blank.

*** Limit of Quantitation (LoQ) is the lowest concentration that can be detected with 30% within-laboratory CV%.

13. Disposal

All samples and materials shall be disposed of according to local law and regulations. All samples, used cassettes and dilution tubes shall be disposed of as biological, potentially infectious materials. Paper, carton and pouches from LUCIA Foal IgG 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.

14. 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 .

<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 Foal IgG 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 Foal IgG 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 Foal IgG Cassette. • If the problem reoccurs, contact support@labmaster.fi.

15. References

- i. Metzger N, Hinchcliff KW, Hardy J, Schwarzwald CC, Wittum T. Usefulness of a commercial equine IgG test and serum protein concentration as indicators of failure of transfer of passive immunity in hospitalized foals. *J Vet Intern Med.* 2006;20(2): 382–387.
- ii. CLSI EP05-A3. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition.* CLSI document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.
- iii. CLSI EP17-A2. *Evaluation of Detection Capability of Clinical Laboratory Measurement Procedure; Approved Guideline – Second Edition.* CLSI document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

16. 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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