Labmaster LUCIA™ Foal IgG Kit

Product number: LM431, LM497

Contents

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).

Product Number	Tests/Kit	Measuring Range	Unit	Measuring Time
LM431	10	100–2500 whole blood 100–1500 serum, plasma	mg/dL	6 minutes
LM497	20			

3. Suitable Sample Material

Sample Material	Blood Collection Tube	Notice	Sample Volume	Diluted Sample Stability
Whole blood in	**EDTA tube**	Mix whole blood by inverting the tube several times.	10 µL	1h in room temperature
Whole blood in	**Li-Heparin tube**	Mix whole blood by inverting the tube several times.		
Plasma separated from	**EDTA tube**	Multiply result by factor 0.6		
Plasma separated from	**Li-Heparin tube**	Multiply result by factor 0.6		
Serum	**Serum Tube**	Multiply result by factor 0.6		

4. Interpretation of Results

1 mg/dL = 0.01 g/L, 1 g/L = 100 mg/dL

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

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

Component Name	Item No.	Pcs / 10-test kit	Pcs / 20-test kit	Notice
Foal Cassette	MA443	10	20	Contains Tween, disodium tetraborate decahydrate, sodium azide, bovine serum albumin, bovine gamma globulin
Dilution Tube 0.99 mL	SA487	20	40	Contains Bovine serum albumin, sodium azide
Foal NFC Card	LA434	1	1	For multiple use, do not discard after measurement. Contains lot specific calibration information. **Do not use with other lots.**
Instructions for Use	LA455 / LA633	0	1	See also instructional video at www.labmaster.fi.

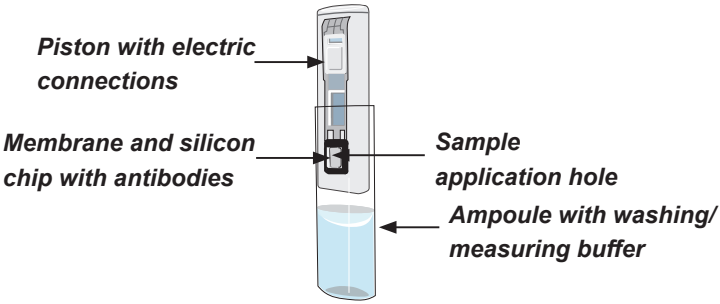
Materials Required but not Provided with the Kit

Product Name	Item No.
Labmaster LUCIA™ Vet analyzer	LM127
Labmaster LUCIA™ Vet analyzer instructions for use	LM128
Recommended: 10 µL Single Volume Pipette	LM510
Recommended: 10 µL Filter tip rack	LM511

6. Storage

Store LUCIA Kit at +2 ... +8 °C.

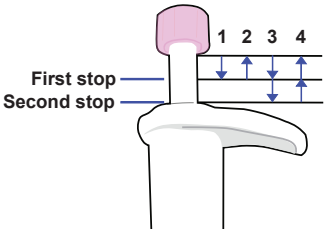
7. Cassette Components



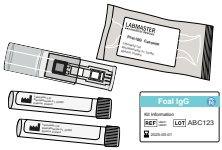
Labmaster LUCIA™ Cassette

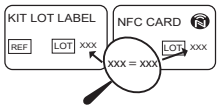
8. Guide to Pipetting

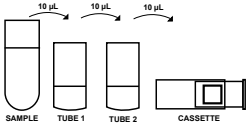
1. Press the plunger to the first stop.
2. Insert the pipette tip just under the surface of the liquid and slowly release the plunger up.
3. Dispense the liquid by pressing the plunger to the first stop. After a delay of approximately one second, continue to press the plunger all the way to the second 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.



9. Assay Protocol







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

Check the NFC Card and component lots

Before measurement, ensure that NFC Card lot information corresponds to Kit lot, Cassette and Dilution Tube lot numbers.

Take components to room temperature 30 min prior to use.

10. Detailed Assay Instructions

Dilute the Sample, 1st Dilution

1. Mix and Mark

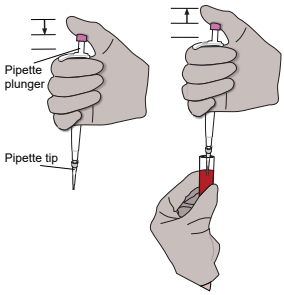
Take 2 tubes and mark tubes and caps with numbers 1 and 2.

Mix the whole blood sample.

2. Aspirate Sample

Place unused pipette tip onto the pipette. Press the plunger down to the first stopper. Insert the pipette tip just under the surface of the liquid and smoothly release the plunger up.

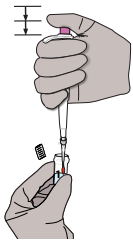
Carefully withdraw the tip from the liquid, touching it against the edge of the container to remove any excess liquid or wipe away any residual sample from outside of the tip.



3. Dispense Sample

Dispense the sample into tube 1.

Insert the filled tip just under the surface of the liquid in tube 1 and press the plunger all the way to the second stop.



4. Mix Sharply

Close dilution tube 1 with cap 1 and turn the tube sharply upside down at least 5 times.

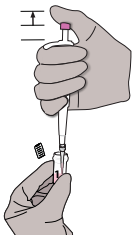
Do not shake the dilution tube.

Dilute the Sample, 2nd Dilution

5. Aspirate Sample from Tube 1

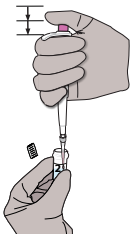
Place unused pipette tip onto the pipette. Press the plunger down to the first stopper. Insert the pipette tip just under the surface of the liquid and smoothly release the plunger up.

Carefully withdraw the tip from the liquid, touching it against the edge of the container to remove any excess liquid or wipe away any residual sample from outside of the tip.



6. Dispense the Sample into Tube 2.

Insert the filled tip just under the surface of the liquid in tube 2 and press the plunger all the way to the second stop.



7. Mix Sharply

Close the dilution tube 2 with cap 2 and turn the tube sharply upside down at least 5 times. Do not shake the dilution tube.

Measurement

8. Check Cassette Ampoule

Open the pouch containing the 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.

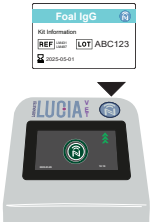
After cassette ampoule has been checked, use the cassette.

Scan the QR code and watch an instructional video on how to handle air bubbles and foam in the test cassette.

9. Type Patient ID and Read NFC Card

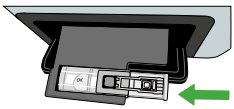
Select the veterinary patient sample measurement icon on LUCIA Analyzer's display, enter veterinary patient ID and read the NFC card as instructed in the Labmaster LUCIA™ Instructions for Use.

NOTE: the diluted sample has to be dispensed into the cassette during the 1-minute time window after the NFC Card has been read.



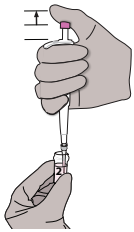
10. Put Cassette onto the Tray

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



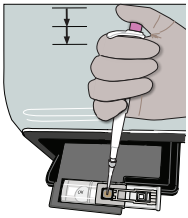
11. Aspirate Sample from Tube 2

Place unused pipette tip onto the pipette. Press the plunger down to the first stopper. Insert the pipette tip just under the surface of the liquid and smoothly release the plunger up. Carefully withdraw the tip from the liquid.



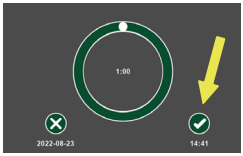
12. Dispense the Sample to the Cassette

Place the pipette tip close to the membrane and press the plunger all the way to the second stop. 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.



13. Start the Measurement

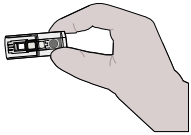
Immediately after adding the sample, start the measurement by selecting the Accept icon on the display.



14. Remove the Cassette and Check It

After the measurement is completed, the result will be shown on the analyzer's display, and the door opens and the tray comes out. Remove cassette from the tray.

Check that the silicon chip is not covered by large air bubble or by foil.

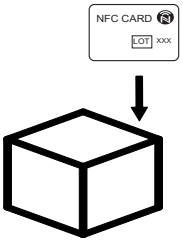


15. Read the Result

Note: If serum/plasma sample was used, multiply the result by factor 0.6.

16. Return NFC Card to the Test Kit

Place the NFC Card back into the correct kit box.



11. 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 Labmaster LUCIA™ Vet 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 pouch contains a desiccant. This material shall not be used in the assay. Discard the desiccant.
- Disposal: See section 14.

Analytical Precautions

- Do not use kit components after the expiry date printed on the kit label.
- Do not mix components with other kit lots.
- NFC Card is lot specific and should be used only for tests from the same kit lot. If NFC Card is lost, a new card can be requested from support@labmaster.fi.
- Cassettes, Tubes and pipette tips are for single use. Do not use already used cassettes or tubes.
- The 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 15.
- 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 the Cassette soon 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.
- 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).

12. 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.

13. Quality Control

Both the Labmaster LUCIA™ Vet Analyzer and LUCIA Kit are factory calibrated. The use of control material is advised to assure the day-to-day validity of results. Use a commercial 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.

14. 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 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.

15. 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 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.

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

17. 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.

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