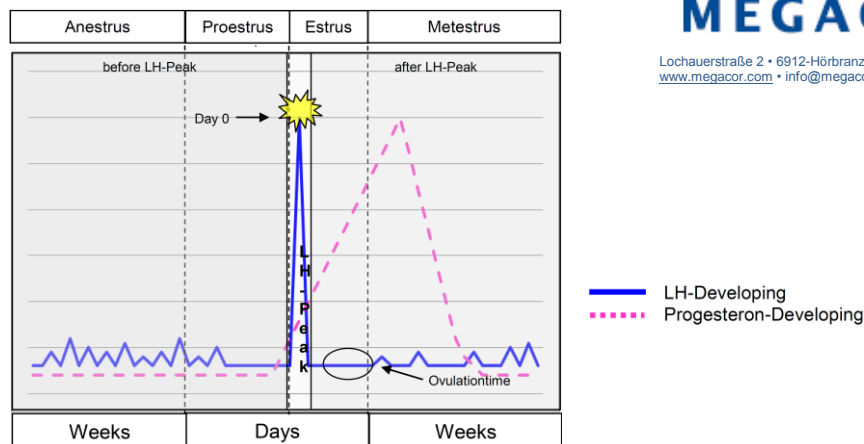


LH-chart in the cycle of bitches



	before LH-Peak		LH-Peak	after LH-Peak	
LH -Test	variable negative - positive if positive, repetition of the test 2 h later => negative		positive repetition of the test 2 h later => positive	negative repetition of the test 2 h later => negative	
LH-Value ng/ml	pulsatile LH-dumping fluctuates between < 1 und > 1		Preovulatory LH ↑ > 1	LH – Basal value < 1	
Cycle state	Early Proestrus	Late Proestrus	Estrus	Early Metestrus	Late Metestrus
Vaginal cytology	Parabasal/Basal/Intermediate cells Mainly Erythrocytes	mainly Superficial cells and Erythrocytes	> 90% Superficial cells „acaryote clods“ Background „clear“	Superficial cells ↓ ↑Parabasal/Intermediate cells, partly neutrophile Granulocytes	↑ Parabasal/Intermediate cells Superficial cells ↓ < 20%
Vaginoscopy	Rose mucosa/ ↑ oedema Sanguinary secretion	Pinkish mucosa/ ↑↑ oedema Sanguinary secretion	Pale mucosa/oedema maximal Clear, less secretion	Pinkish mucosa hyperplastic, sticky yellowish mucous secretion	Rose mucosa/moistly, lucent Marginal – no secretion
Bearing	partial toleration of male dogs	Toleration of male dogs	Toleration of male dogs + mating	Rejection of male dogs	
Progesteron value ng/ml	Basal value <0,5	↑ up to ca. 1	↑ increase > 2 – 4	Ovulation: 4-10	post Ovulation: > 10

LIABILITY

The entire risk due to the performance of this product is assumed by the purchaser. The manufacturer shall not be liable for indirect, special or consequential damages of any kind resulting from use of this product.

DIAGNOSTIK
MEGACOR

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FASTest® LH ad us.vet.
IN VITRO DIAGNOSTICUM

Testkit for the qualitative Detection of luteinizing Hormon (LH) in Serum of Dog and Cat

Instructions for use

1. INTRODUCTION

FASTest® LH is based on rapid immunochromatographic technique („lateral flow“) for the detection of **luteinising Hormon (LH) in Serum of dogs and cats**. LH belongs to the sexual hormones which is available in marginal volume in bitches and queens generally. The LH-value is increased in a dramatically way during the so-called LH-peak on the verge of ovulation or few days after an effective gonadektomie at bitches and queens for an enduring time. Via **FASTest® LH** an in-clinic detection of an elevated LH-value is possible.

Thus **FASTest® LH** is a reliable in-clinic screening test **for timing the ovulation time/mating resp. artificial insemination time in the bitch, for determination of the whelping date** and for the differentiation **between fertile (intact ovar) and infertile (ovariectomized resp. chemical castrated) dogs and cats**.

INDICATION I: Determination of LH-Peak

At the so-called LH-Peak there is a broad increase of LH-value, which will decrease 24-40h after LH-Peak to the basal value. Ovulation will occur 24-72h after LH-Peak.

Today, the LH-Peak is distinguished as the most accurate method for the detection of the canine ovulation time and for the determination of the mating time. The LH-Peak - which is named as „Day 0“ – is used for the determination of the whelping date: Gestation length Ø 65 days +/- 1 day.

For the detection of the LH-Peak the LH-measures should be started at the 4th or 5th day of the proestrus or if the vaginal cytology shows a cornification of ≥ 50% (cornification is identified as cells with a roughened angled or acaryote cell wall), every day at the same time.

For being sure of starting the test period in time (before ovulation time) there should be done a vaginal cytology, vaginoscopy and/or measurement of progesterone. If the test period begins after LH-Peak **FASTest® LH** gives a negative result and the progesterone value is already increasing.

If the **FASTest® LH** gives a positive result, the possibility of a pulsatile fluctuation should be evaluated, which is normal in the proestrus. In this time the progesterone value is in a low level. Because of this a positive test should be repeated after 2 hours with a new sample.

INDICATION II: fertile/not castrated or infertile/castrated cats and dogs:

Fertile queens and bitches show a **LH concentration of < 1ng/ml**, except in the course of preovulatory LH increase/LH Peak.

In case of successful/complete ovariectomized bitches or queens the LH concentration will increase due to the lack of negative feed-back (Oestrogen decrease) already from day 10 after castration. This high LH levels will be stable over a period of years. **FASTest® LH** shows a positive result.

For the exclusion of the LH peak or pulsatile LH fluctuations a positive test result should be repeated after 2h (CATS) or 24 h (DOGS). Two positive tests will proof a castrated queen/bitch.

2. TEST PRINCIPLE:

Negative: < 1 ng/ml

<- Cut-off ->

Positive: ≥ 1 ng/ml

LH-molecules in the serum will bind to specific monoclonal Anti-LH antibodies forming an Antigen-Antibody-Complex! Migrating ("lateral flow") along the nitrocellulose membrane these specific antigen-antibody-complexes were bound from fixed, gold labeled monoclonal Anti-LH-Antibodies forming a more or less intensive pink-purple TESTline „T“. The correct test procedure is proved by the occurrence of a second, intense pink-purple CONTROLline line at the CONTROLzone.

3. TESTKIT COMPONENTS:

1 Testkit **FASTest[®] LH** contents:

- 2/5/25 Test cassettes with monoclonal Antibodies
- 2/5/25 disposable plastic pipettes
- Instruction for use

4. STORAGE AND SHELF LIFE:

- Store at room temperature (15–25 °C)
- When stored correctly the product can be kept up to expiry date.
- Avoid excessive heat or cold: DO NOT FREEZE!

5. INFORMATIONEN ON TEST SAMPLE MATERIALS

- Only use Sera for LH-determination
- Hemolyzed and/or lipaemic Serum samples shouldn't be used
- **Sera should be tested directly after removal! Not cooled samples (15-25°C)** could be stored up to 2 hour prior to testing! Short term storage up to 24 hours at **2-8°C**, long term storage (serum) at min. **-20°C** for an undefined time
- All test components / samples has to be allowed to warm to room temperature (15 to 25°C)

6. SPECIAL INFORMATION:

- For veterinary use only.
- **FASTest[®] LH** can be used for dog and cat only.
- Do not remove any test components (room temperature!) from their individually sealed pouches until immediately before their use.
- Follow Instructions for use precisely.

7. TEST PROCEDURE:

1. Remove the Test cassette from the foil pouch, label it with a patient name or ID number and make sure that the Test cassette is on a level surface.

2. Mix Sera homogenous and add 3 drops (ca. 120-150µl) of sera into the sample window „S“ with the enclosed disposable plastic pipette. Please attend to the information in **5. Information on Test Sample Material.**

3. No need for buffer diluents!



4. Read results after an incubation time of 20 minutes. Addicted by LH concentration test result could be occur within these 20 minutes. Any results after this time interval may not be interpreted!

8. INTERPRETATION of TEST RESULTS:

NOTE: Every interpretation of Test results should be pulled together to any available information (anamnesis, clinic, etc.).

Color intensity of TEST line „T“ in proportion to CONTROL line „C“ is important for interpretation of test results correctly.

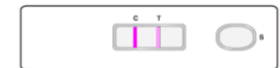
POSITIVE LH-Test result:

If a clearly signed pink/purpur TESTline „T“ with the same or stronger intensity as the clearly signed pink/purpur CONTROLline „C“ is shown, the test indicates the presence of LH level ≥ 1 ng/ml.



NEGATIVE LH Test result:

If no clearly signed pink/purpur TESTline „T“ is shown or just with a lower intensity than the clearly signed pink/purpur CONTROLline „C“, the test indicates the presence of LH **<1 ng/ml.**



Inconclusive TEST result:

In case of only one weak to strong and clearly signed pink/purple line in the TEST zone (T) or no pink/purple line neither in the TEST zone (T) nor in the CONTROL zone (C) the test is not valid signifying. The test has to be repeated using a new test cassette.

