Version 03/2018

*FAST*est® RELAXIN ad us. vet.

***In vitro* diagnosticum**

Test-kit for the qualitative detection of Relaxin in plasma or serum of dog and cat

INSTRUCTIONS FOR USE

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® RELAXIN** contains:
- 2, 5 or 25 test cassettes coated with monoclonal antibodies
- 1 dropper bottle **A** with 1.0 ml or 3.0 ml buffer diluent
- 2, 5 or 25 disposable plastic pipettes
- 1 instructions for use

STABILITY AND STORAGE

Store at 15–25 °C

Expiry date – see label

APPLICATION AND ABBREVIATIONS

For veterinary use only

LOT Lot number

In vitro diagnosticum

! Do not use test-kit components from different kits, lot numbers or beyond stated expiry date.

Follow instructions for use precisely

B – TEST line, **C** – CONTROL line, **LF** – Lateral flow

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 the use of this product.

2. INTRODUCTION

Relaxin is the only known pregnancy-specific hormone of the carnivores (dog and cat) that informs about the presence of relaxin producing placenta tissue. Therefore, it is perfectly suitable for an indirect proof of pregnancy in the female dog and cat.

In all carnivores, relaxin production is performed mainly by the placenta (syncytiotrophoblast). In pregnant bitches, relaxin production starts with the nidation of the fertilized egg in the uterus wall (15 days after ovulation). In the female dog, relaxin can be detected in the serum for the first time in the 4th week of pregnancy (soonest from day 22–28 post ovulation), in the cat for the first time from day 15 of pregnancy on, then increases very fast and remains on a high level during the pregnancy.

The relaxin concentration can remain demonstrably increased up to 14 days after beginning of foetus resorption (up to day 28–30 post ovulation, without clinical symptoms) or abort (from day 28–30 post ovulation on, with clinical symptoms) due to active trophoblast leftovers, then it still leads to positive test results. Therefore, the test cannot make a statement about the number of puppies, their vitality or about beginning resorption of one or more puppies.

Due to the exclusive incidence of measurable relaxin amounts in plasma or serum of gravid dogs and cats, ***FAST*est® RELAXIN** can be applied as indicator both for an existing pregnancy and for monitoring of the pregnancy during suspicion of spontaneous abort as well as for ruling out a pseudogravidity.

Despite all that, pregnant bitches should be under the supervision of a veterinarian, meaning regular control supported by ultrasound and/or X-rays in order to monitor the pregnancy or to determine the number of foetuses that are present.

3. INFORMATION ON THE SPECIMEN MATERIAL

Approximately **80–100 µl (2 drops of attached plastic pipette) 15–25 °C warm plasma (P**, anticoagulated with heparin**) or serum (S)** are needed.

Exclusively use warm heparin plasma (NO EDTA or citrate plasma and NO native blood)!

Mix the sample material well before use!

Non-cooled (**15–25 °C**), P and S should be tested **within 4 hours**! Storage exclusively **at minimum −20 °C**.

Keep in mind that the sample material, as well as all used test-kit components, should have reached **room temperature** at the time of application.

Endogeneous and exogeneous interfering substances of the sample (e.g. albumin, fibrinogen, lipids, CRP, heterophilic antibodies, especially type IgA, as well as viscosity, pH-value and excess heparin) **can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on B and C.**

4. SPECIMEN COLLECTION AND PREPARATION

- No specimen preparation necessary.
- **CAREFUL:** Partially filled and/or insufficient mixed heparin tubes could create invisible microclots resulting in lateral flow delay and/or unspecific reactions (e.g. greyish shadow like lines).

5. TEST PROCEDURE

1. Remove the test cassette from its foil pouch shortly before use. Place it on a flat surface.
2. **Express 2 drops** (ca. 80–100 µl) **of sample** into the sample window A **using the disposable plastic pipette** (fig.1).
3. Hold the buffer dropper bottle **A** vertically and express **2 drops of buffer diluent (ca. 80–100 µl)** into the sample window A (fig.2).
4. Add 1 additional drop of buffer diluent into the sample window A if there is no beginning LF visible within 1 minute after adding the buffer diluent.

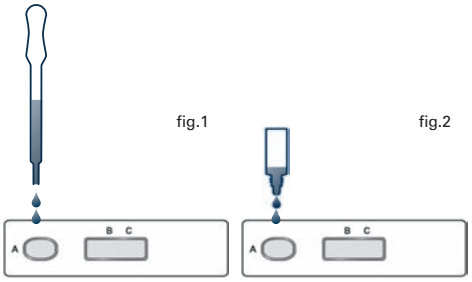


fig.1 fig.2

6. READING OF THE TEST RESULT

Read the test result **10–30 minutes** after the two drops of buffer diluent have been added into the sample window A.

POSITIVE TEST RESULT (fig.3)
A pink-purple coloured TEST line **of any intensity** (varying from very weak to strongly intensive) and a pink-purple CONTROL line appear.

NEGATIVE TEST RESULT (fig.4)
Only a pink-purple CONTROL line appears. This line indicates, irrespective of its intensity, that the test has been performed properly.

INVALID TEST RESULT
No CONTROL line visible. The test should be repeated using a new test cassette.

fig.3
POSITIVE TEST RESULT

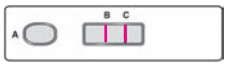
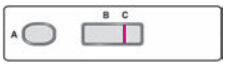


fig.4
NEGATIVE TEST RESULT



7. PRECAUTIONS FOR USERS

- Label sample material and associated test cassette to ensure a precise assignment.
- Use a new pipette for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid skin contact and/or ingestion.
- The sample material must be seen as potentially infectious and disposed of accordingly, together with the used test-kit components.

8. TEST PRINCIPLE

The ***FAST*est® RELAXIN** is based on an immunochromatographic "sandwich principle".

The Relaxin molecules of the sample will bind to monoclonal mobile antibodies, which are bound to gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these antigen-antibody complexes are bound by immobilised highly specific monoclonal anti-Relaxin antibodies, producing a pink-purple coloured TEST line (**B**).

A correct test procedure will be indicated by a second, pink-purple CONTROL line (**C**).

9. INFORMATION FOR THE INTERPRETATION

- The interpretation of the test result should always be based on anamnestic and clinical data as well as the therapy and prophylaxis possibilities.
- Any non-described colour or contour variation of B and C (e.g. greyish, shadow-like lines) or after more than 30 minutes has to be considered as unspecific reaction and therefore as negative test result.
- Due to anticoagulated whole blood and/or red hemoglobin background of the test membrane, caused by hemolytic blood samples, the visibility of B, especially in case of weak positive samples, could be from bad to not visible.
- A negative test result **after day 26 post ovulation** excludes a pregnancy with high probability (e.g. failed mating).
- Due to the variables "day of mating", "degree of ovum maturity" and "viability of the semen" (Ø up to 5 days), day of mating must not correspond to the day of conception. Therefore, a **negative test result before day 26 post ovulation** requires a second test 1 week later to confirm the diagnosis.

Possible reasons for false negative test results

- Inadequate storage of the sample material (see issue 3).
- Non-awaiting of the prescribed period of incubation of **10–30 minutes**.
- Only one test with a negative test result before day 26 post ovulation (LH peak) was done, a recommended second test one week later to confirm the first test was not done.

Possible reasons for false positive test results

Relaxin production in **still active remnants of the trophoblast**

- after beginning of resorption of all foetuses (mostly up to day 28–30 post ovulation, without clinical signs).
- after beginning of complete abortion (mostly after day 28–30 post ovulation, with clinical signs) **up to 14 days later** (due to unpublished preliminary information).

6912 Hörbranz – AUSTRIA
www.megacor.com

Latest scientific data prove the possibility to detect relaxin in the plasma or serum of the cat earliest from day 26–29 of pregnancy.