CANINE AND FELINE PREGNANCY TEST KIT

I. GENERAL INFORMATION

WITNESS™ RELAXIN is intended to determine pregnancy in the bitch and queen, as well as to distinguish between pseudopregnancy and real gestation in the bitch. The test measures Relaxin levels in plasma and serum samples. The presence of significant amounts of this hormone is a reliable indicator of pregnancy.

The WITNESS™ RELAXIN test provides an early, inexpensive and reliable way to determine success or failure of a planned mating or unwanted exposure.

II. PREGNANCY DETECTION

Canine: Relaxin can be detected in biological samples soon after implantation of the fertilized egg, which occurs about 18 days after LH surge. Relaxin is first detectable by WITNESS™ RELAXIN during the fourth week of pregnancy (from D22 to D28 after ovulation), reaches its highest level in the 6th-8th weeks, and then declines prior to parturition.

Feline: Some pregnancies may be detected as early as 25 days post-mating, while others may not test positive until after 31 days. It is recommended to test after this date if a previous result was negative.

Occasionally, false positive results may occur in non-pregnant queens with elevated Relaxin levels due to cystic ovaries.

III. TEST PRINCIPLES

WITNESS™ RELAXIN is a simple test based on Rapid Immuno Migration (RIM™) technology that uses the combination of two anti-Relaxin antibodies to quickly identify this hormone in biological samples (serum or plasma) from the bitch and queen.

Colloidal gold particles sensitized with an anti-Relaxin antibody bind to Relaxin molecules present in the sample.

The formed complex migrates along a membrane. The complex is then captured on a sensitized reaction line (second antibody) where its accumulation causes the formation of a clearly visible pink/red band.

A pink/red band in the control window (3) ensures that the test was performed correctly.

IV. SAMPLE COLLECTION

- The test can be performed on serum or plasma (anticoagulated with EDTA, sodium citrate or heparin).
- Always collect samples with a sterile needle and syringe.
- Hemolysis does not significantly interfere with the test, but strongly hemolyzed samples may partly obscure a weak positive band.

V. SAMPLE STORAGE

- Samples should preferably be tested immediately after collection but not longer than 4 hours after collection, if stored at room temperature.
- If testing is further delayed, samples should be kept refrigerated (up to 2 days at +2 °C to 8 °C; 35 °F to 46 °F).
- For long term storage, samples should be kept frozen (-20 °C; -4 °F or colder).

VI. KIT CONTENTS

- 5 Pouches, each containing 1 test device and desiccant.
- 5 Pipettes.
- 1 Saline Buffer bottle (2 mL).
- Instructions for use.

VII. PRECAUTIONS

- Do not use this kit or any of its components after the expiration date.
- Kit should be stored at +2 °C - 25 °C (35 °F - 77 °F). Kit should not be frozen.
- Use the test immediately after the pouch is first opened (within 10 minutes).
- Avoid touching or damaging the membrane in the sample well or the results windows.
- The WITNESS™ device should be placed on a flat, horizontal surface while performing the test.
- Use a separate pipette for each sample.
- Hold pipette and buffer bottle vertically when dispensing sample and buffer respectively.
- Handle all samples as biohazardous material.
- For veterinary use only.

Note:

Prior to use, test and control bands appear yellow. The bands are dyed yellow for quality control purposes. The dye does not interfere with the test results and will wash away while the test is developing.

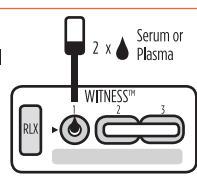
VIII. TEST PROCEDURE

Important: Allow sample and buffer drops to fall onto the membrane in the sample window. Do not touch pipette tip, buffer bottle tip, or the sample or buffer drops directly to the membrane.

1. SAMPLE APPLICATION

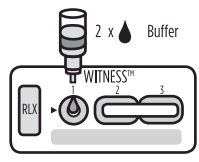
- Tear open a pouch provided and place the test device on a flat horizontal surface.
- Holding the provided pipette vertically, dispense two drops of sample to the test well.

(Do not use whole blood).



2. BUFFER DISPENSING

- Check that the sample has fully absorbed into the membrane.
- Remove the cap from the buffer bottle, hold it vertically and add two drops of buffer to the test well.
- Leave the test device flat during migration of sample/reagent complex through the results window.

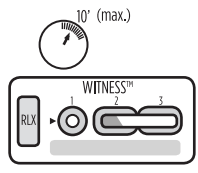


3. READING TEST

After 10 minutes, observe the presence or absence of pink/red bands in the results windows (2) and (3).

Note:

- *It is possible to read the test before 10 minutes if two pink/red bands are clearly visible in the results windows (2) and (3).*
- *The presence of only one band in control window (3), prior to the end of the development time (10 minutes) does not mean that the test is complete, as a test band may appear more slowly than the control band.*



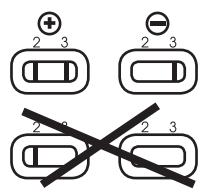
IX. RESULTS

Valid Results

Test is valid if a pink/red band is present in control window (3).

Interpretation of Results

- Positive: One band in reading window (2), with one band in window (3): sample is positive for Relaxin.
- Negative: No band in reading window (2), with one band in window (3): sample is negative for Relaxin.
- Invalid test: No pink/red band in control window (3).



Positive Samples: All positive results confirm pregnancy.

Negative Samples: A negative result means that Relaxin is not present in the sample (no pregnancy) or that its level is too low to be detected (too early to confirm a pregnancy status). Two negative results at least one week apart may be required for confirmation of non-pregnancy, especially when date of ovulation (or mating) is unknown. Non-pregnancy can be certainly confirmed only starting from day 27 after bitch's ovulation (31 days post-mating in queens).

SYMBOL DESCRIPTIONS

	Use by Date (expiration date)	EC REP	Authorized Representative in the European Community
LOT	Batch Code		Consult Instructions for Use
SN	Serial Number	IVD	*In Vitro* Diagnostics
	Temperature limitations (storage temperature range)		Manufacturer
			Date of manufacture

zoetis

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EC REP

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