InSight V-IA®

Canine Relaxin (C-RLN) Rapid Quantitative Test

INTENDED USE

The InSight V-IA Canine Relaxin (C-RLN) Rapid Quantitative Test is a fluorescence immunoassay used with the InSight V-IA Veterinary Immunoassay Analyser for the quantitative determination of relaxin concentration in canine serum or plasma. The test is used to diagnose early pregnancy in dogs.

For *in vitro* diagnostic use only. For veterinary use only.

TEST PRINCIPLE

1.This test employs a quantitative double antibody sandwich fluorescence immunoassay technique.

2.The fluorescent signal intensity reflects the amount of C-RLN captured and is processed in InSight V-IA Veterinary Immunoassay Analyser. The C-RLN concentration is expressed in ng/mL.

WARNINGS AND PRECAUTIONS

1.This kit is for in vitro diagnostic use only.

2.The Lot No. of all the test components (test device, ID chip and buffer) must match each other. Do not mix components from different kit lots.

3.Inspect the packaging and labels before use. Do not use if the pouch is broken, torn, unsealed or the cartridge/buffer is damaged.

4.Carefully follow the instructions and procedures described in this insert.

5.Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use. Do not use if the pouch or the device itself is damaged, torn or unsealed.

6.A buffer tube should be used for processing one sample only.

7.One pipette tip should be used for one sample only.

8.Do not touch the test area of the test device .

9.All samples and used test materials are considered potentially infectious. The used pipette tips, buffer tubes, test devices and samples must be handled carefully and disposed of in accordance with local regulations and procedures.

10.Serum or plasma samples must be used. Do NOT use whole blood as inaccurate results may report.

11.Do NOT use a serum separator tube as inaccurate results may report.

MATERIAL

Material Provided

Each box contains:

- 10 individual sealed pouches, each containing:
  - a test device
  - a desiccant pouch
- Pipette tips
- 1 test device ID Chip
- Instructions for use
- 10 tubes of Tris-HCl buffer

Material Required But Not Provided

- InSight V-IA Veterinary Immunoassay Analyser
- Transfer pipette
- Timer
- Centrifuge

STORAGE AND STABILITY

1.Store the test kit at 4°C~30°C up to the expiration date.

2.Once the pouch is opened, the test should be performed within an hour.

3.If removed from refrigerator, allow 30 minutes for the test to attain room temperature before testing.

SAMPLE COLLECTION AND PREPARATION

The test can be performed with either serum or plasma.

1.Following standard phlebotomy venipuncture procedure, collect whole blood sample using a blood collection tube.

If a plasma sample will be used, use a blood collection tube containing EDTA anticoagulant. If a serum sample will be used, use a blood collection tube without anticoagulant. Do not use a serum separator tube.

2.Separate serum or plasma from blood within 2 hours after blood collection. If a sample appears to be severely haemolysed, another sample should be obtained and tested.

3.The test should be performed immediately after sample collection. If the test cannot be performed within 2 hours after blood collection, store the sample at 2°C~8°C for no longer than 48 hours. For long-term storage, samples should be kept below -20°C.

Bring all materials to room temperature before use. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly. Only clear, non-haemolysed samples should be used.

TEST PROCEDURE

Refer to the InSight V-IA Veterinary Immunoassay Analyser User Manual for complete instructions for use of the analyser.

1.Set the test device on a clean, level horizontal surface.

2.Make sure that the test device Lot No. matches with the ID Chip No. Insert the ID Chip into the analyser. Be aware not to touch the insertion tip of the ID Chip. Press 'Read ID Card' on the test screen.

3.Pipette 75µl of prepared sample into the buffer, gently mix well. Vigorous agitation and foaming should be avoided.

4.Pipette 75µl of mixed sample dilution to the sample well of the test device. Avoid forming bubbles.

5.Please refer to Section V in the InSight V-IA Veterinary Immunoassay Analyser User Manual for details.

a) **Quick Test Mode:** Set the timer for 15 minutes, start the timer immediately after adding the sample mixture to the sample well. Once the timer has counted down, insert the test device immediately into the cartridge holder of the analyser and click 'Test'. The analyser will scan the test device automatically and show the test result.

b) **Standard Test Mode:** Insert the test device into the cartridge holder of the analyser immediately after adding the sample to the sample well, click 'Test'. The analyser will start to countdown and read the test result automatically.

6.Results are displayed on the main screen and printed automatically.

INTERPRETATION OF RESULTS

The InSight V-IA Veterinary Immunoassay Analyser calculates relaxin test results automatically and displays the concentration of relaxin on the screen. For further information, refer to the User Manual for the InSight V-IA Veterinary Immunoassay Analyser.

Detection Range: 0.5-50 ng/mL

Reference Range:

Signification	ng/mL
Non-pregnancy period	<3
Pregnancy	≥3

*The recommended testing time is 25-30 days after mating. Due to individual differences, if a negative result occurs, the testing time may be too early. Re-test after 5 days.

Each laboratory should establish a reference range that is representative of the population to be evaluated.

QUALITY CONTROL

Each InSight V-IA C-RLN Rapid Quantitative Test contains an internal control for routine quality control requirements. This internal quality control is performed each time a patient sample is tested. If an invalid result from the internal control occurs, the analyser will display an error message, indicating that another test should be performed.

LIMITATIONS OF PROCEDURE

1.This test is developed for testing canine serum or plasma only.

2.The results of InSight V-IA C-RLN Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed accordingly.

3.The performance of the test is highly sensitive to the storage and handling conditions of kits and samples.

4.There is the possibility that factors such as technical or procedural errors may interfere with the test and cause erroneous results.

5.Sample interference (haemolysis/lipaemia/icterus) may cause abnormal results.

MANUFACTURED BY

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