Canine progesterone (cProg) Rapid Test

PRODUCT NAME

Canine progesterone (cProg) Rapid Test

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

Used for in vitro quantitative test of Canine Progesterone (cProg) concentration in serum or plasma. Clinically, It is mainly used in canine for ovulation, mating time and miscarriage diagnosis.

TEST PRINCIPLE

This test employs a quantitative competitive fluorescence immunoassay technique. Take the sample and add it into the sample dilution, mix it, then drop the mixed sample into the well of the cartridge, The cProg in the sample reacts with a fluorescently labeled antigen coated on the glass fiber to form a complex substance. Under chromatography, the complex substance and unreacted fluorescently labeled antibody diffuse forward along the nitrocellulose membrane, and the complex substance is captured by the corresponding antigen fixed on the nitrocellulose membrane detection line. The more analytes in this test, the less complexes formed by reaction with fluorescently labeled antibodies, and the less fluorescently labeled antibodies accumulate on the detection line. The cProg concentration is expressed ng/ml as the unit.

MATERIAL PROVIDED

Each kit contains a cartridge, buffer, NFC card, and instruction manual.

(1) The cartridge consists of a strip, a plastic shell. The strip consists of a sample pad, nitrocellulose film, absorbent paper, PVC board and other testing auxiliaries.

(2) The main ingredient of the sample dilution is Tris-HCl buffer.

STORAGE AND STABILITY

Store the cartridge at 4~30°C up to the expiration date, the shelf life is 24 months. Once the pouch is opened, the test should be performed within an hour.
Production date: See the Label
Expiration date: See the Label

APPLICABLE DEVICE

Only suitable for testing with the Multi-functional Analyzer for Vet (EHVT-50).

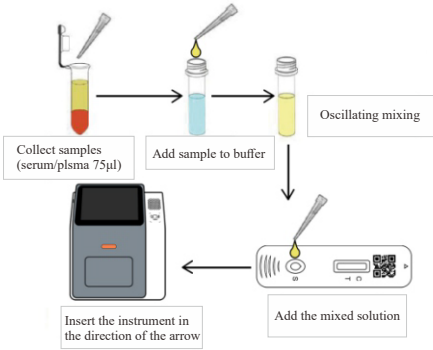
SPECIMEN REQUIREMENTS

The test can be performed with serum or plasma,EDTA anticoagulated plasma is recommended.
Serum and plasma should be centrifuged immediately after collection to avoid

hemolysis. If the test cannot be performed within 2 hours after centrifugation, store the sample at 2~8°C for no longer than 48 hours.

TESTING METHTOD

1. Please refer to the instrument operation manual before use.
2. Take out the NFC card, make sure that the cartridge lot No. matches with the NFC card No. Hold the NFC card close to the NFC sensing area of the instrument and do not remove it until the instrument prompts a successful reading. The NFC card in each reagent box only needs to be registered once. When you activate a new box of reagents, you need to register the information of the new NFC card again.
3. If removed from the refrigerator, allow the test to attain room temperature before testing, and the test should be performed at room temperature.
4. Tear the pouch and take out the cartridge. Pipette 75 μL of the sample, add the sample to the buffer, and upside-down 8~10 times until well mixed and pipette 75μL then drop into the well of the cartridge.
5. “Quick Test” model: Start the timer right after adding the sample mixture to the sample well. Leave the cartridge at room temperature for 15 minutes. Once the reaction time is over insert the cartridge immediately into the holder of the meter and click “Test”. The device will read the reagent card automatically and show the test result.
6. “Standard Test” model: insert the cartridge into the device holder right after adding the sample, click “Test”. The meter will start to countdown and read the test result automatically.



INTERPRETATION OF RESULTS

1. After the test is completed, the test result will be displayed on the main screen of the instrument.
2. If the sample is insufficient or the sample does not completely crawl across the test line, the device will prompt “No sample or the volume of sample is insufficient”. In this case recommends a new test.
3. There is the possibility that factors such as technical limits or operational errors. It should be evaluated with all clinical and laboratory data available if not agree with the clinical evaluation, additional tests should also be performed accordingly.

LIMITATIONS OF TESEING METHODS

1. The test is developed for testing a canine serum or plasma sample.
2. The test results of the reagent can only be used for a doctor’s or other diagnosis. The result should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should also be performed accordingly.
3. There may be several reasons for false positive results: Some non-specific components in the sample have similar epitopes to capture fluorescently labeled antibodies as progesterone; the presence of non-specific binding to the coated antibody in the sample affects the capture of fluorescently labeled antibodies by the coating line.
4. There may be several reasons for false negative results: Some unknown components shield the epitope from binding to the antibody; the unstable progesterone antigen, which gradually degrades over time and temperature, cannot be recognized by the antibody. Effective test results depend on a good reagent and a sample storage environment.
5. Other factors may also cause incorrect progesterone test results. These factors include technical reasons, operational errors, and other sample factors such as severe hemolysis, severe jaundice, and high lipid content.

WARNINGS AND PRECAUTIONS

1. This kit is for canine use only.
2. This product is a single-use in vitro diagnostic reagent. Do not reuse.
3. All samples and used test materials are considered potentially infectious. Appropriate protective measures should be taken, the blood collection, disposal, storage, test devices and samples must be handled carefully and disposed of in accordance with local regulations and procedures.
4. The card must remain in its original sealed pouch until ready to use. Do not use if the pouch, buffer, NFC card and the cartridge itself is damaged, torn or not fully sealed.
5. Lot Numbers of all the test components (cartridge, NFC card and buffer) must match each other. Do not mix components from different kit lots.
6. Never insert a cartridge whose surface is wet with blood or other liquids into the reader, otherwise the device will be contaminated or damaged. Dispose of used cartridges properly and do not discard them randomly.

7. It should be tested under the specific environment. The cartridge stored at a low temperature needs to be brought to room temperature before opening to avoid moisture.
8. The operation shall be conducted away from vibrations and magnetic fields. The veterinary Immunofluorescence Analyzer may generate minute vibration during use, which should be regarded as normal. Do not remove the NFC card during the test.
9. It is recommended to use fresh samples. If there is obvious hemolysis or blood clots in the sample, it will interfere with the test and cause errors. Please recollect the samples for testing.
10. Inside the pouch desiccant, do not swallow, keep far away from the children.
11. Expired products will affect test results, please do not use.
12. The final result should be issued by a veterinarian after evaluation with all available clinical and laboratory data and clinical symptoms.
13. If you have any questions or suggestions while using, please contact the manufacture.

INTERPRETATION

1. Reference range of Canine Progesterone (cProg):
Detection range : 1~50ng/mL (3.18~159nmol/L)
Reference range: Best breeding period 10~20ng/mL (31.8~63.6nmol/L)
2. The reference range of this product is recommended. Each laboratory should establish its own reference range.
3.There must be a final decision by the veterinarian.
If in any case can not be confirmed using a diagnostic method. Please make a comprehensive evaluation based on clinical symptoms, diagnostic records, and testing results.

PRODUCT PERFORMANCE INDICATORS

1.Accuracy: The relative deviation of the reference for measuring the accuracy of internal control of enterprises is within ±15.0%.
2.Inter-batch precision: The coefficient of variation (CV) is ≤15% when the reference is determined by several kits of the same batches.
3.Batch-to-batch precision: The coefficient of variation (CV) is ≤20% when the reference is determined by several kits of different batches.
4.The linearity of the dose-response curve: In the range of 1~50ng/mL, the linear correlation coefficient of dose-response curve is R>0.95.
5.Interference test: At the test on the following substances of specified concentration, an interference phenomenon is not found.

Bilirubin	400μmol/L
Hemoglobin	5g/L
Triglyceride	15mmol/L

6.HOOK effect: When the concentration of cProg is up to 500ng/mL, there was no HOOK effect.

INDEX OF SYMBOLS

	Sufficient for tests		Use -by date
	Consult instructions for use		Temperature limit
	Date of manufacture		Do not reuse
	Batch code		CE Marking
	Keep away from sunlight		Keep dry
	Manufacturer		Authorized Representative in European Community
	Caution		Do not use if package is damaged and consult instructions for use

Manufacture Information

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