

Canine Cortisol Rapid Test

PRODUCT NAME

Canine Cortisol Rapid Test.

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

Used for in vitro quantitative test of canine cortisol concentration in serum or plasma. Clinically, it is mainly used to diagnose adrenal disorders and evaluate the therapeutic effect.

TEST PRINCIPLE

This test employs a quantitative double antibody competitive fluorescence immunoassay technique to test the cortisol concentration in Canine serum or plasma. Take the sample and add it into the sample diluent, mix well, then drop the mixed sample into the well of the cartridge. The cortisol in the sample reacts with a fluorescently labeled antibody coated on the glass fiber. Under the action of chromatography, the complex substance diffuses forward along the nitrocellulose membrane. During this process, the free cortisol in the sample competes with the cortisol conjugated on the test line for binding to the fluorescently labeled antibody. The more cortisol in the sample, the fewer fluorescent antibodies bind to the test line, resulting in a weaker signal intensity on the test line, which inversely reflects the amount of the cortisol in the sample. The cortisol concentration is expressed in nmol/L as the unit.

MATERIAL PROVIDED

Each kit contains 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

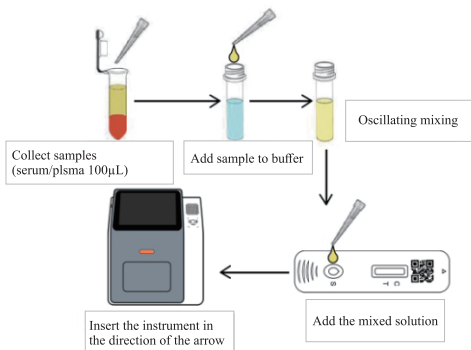
The test can be performed with serum or plasma.

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 METHOD

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 for reagents of the same batch only needs to be read once; if the NFC card information of the batch has been entered, no repeated operation is required.
3. If removed from 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 100 μ L of the sample, add the sample to the buffer, Upside-down 8-10 times until well mixed and pipette 100 μ L 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 cartridge 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 crawled 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 TESTING 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 Veterinarian 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 result: Some non-specific components in the sample have similar epitopes to capture fluorescently labeled antibodies as cortisol; 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 result :Some unknown components shield the epitope from binding to the antibody; the unstable cortisol antigen, which gradually degrades over time and temperature, cannot be recognized by the antibody. Effective test results depend on a good reagent and sample storage environment.
5. Other factors may also cause incorrect cortisol 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 single-use in vitro diagnostic reagent. Do not reuse.
3. All samples and used test materials are considered as 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 number 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 low temperature needs to be balanced to the room temperature before opening to avoid moisture.

8. The operation shall be conducted away from vibration and magnetic field. 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 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

INTERPRETATION

1. Reference range of cortisol in canine blood:

Detection range: 10-1000nmol/L(0.36-36.23ug/dL)

Reference: 16.6-166 nmol/L (0.6-6.01 ug/dL)

-- The reference range of this product is recommended. Each laboratory should establish its own reference range.

2. There must be a final decision by the veterinarian.

3. If in any case cannot be confirmed using a diagnostic method. Please make a comprehensive evaluation based on clinical symptoms, diagnostic records, and testing results.

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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