

Canine NT-proBNP Rapid Test

PRODUCT NAME

Canine NT-proBNP Rapid Test

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

Used for in vitro quantitative test of Canine NT-proBNP concentration in serum or plasma. Clinically, it is mainly used for the assistant diagnosis of canine heart failure.

TEST PRINCIPLE

This test employs a quantitative immunofluorescence sandwich method technique to test the Canine NT-proBNP (cNT-proBNP) concentration in Canine serum or plasma. Take the sample and add it into the buffer, mixture well, then drop the mixed sample into the well of the cartridge, the cNT-proBNP in the sample reacts with a fluorescently labeled antibody coated on the glass fiber to form a complex substance. Under the action of chromatography, the complex substance and unreacted fluorescently labeled antibody diffuse forward along the nitrocellulose membrane, are captured by the cNT-proBNP monoclonal antibody coated on the nitrocellulose membrane test line. The more cNT-proBNP in the sample, the more complexes accumulate on the detection line, and the signal intensity of the fluorescent antibody reflects the amount of cNT-proBNP captured. The cNT-proBNP concentration is expressed pmol/L 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 PBS 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

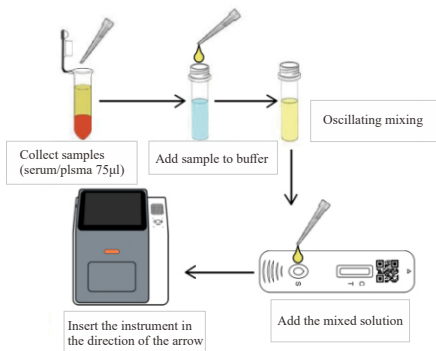
The test can be performed with serum or plasma, EDTA anticoagulated plasma is recommended.

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 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 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 μ L of the sample, add the sample to the buffer, and upside-down 8-10 times until well mixed and pipette 75 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 10 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 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 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 results: Some non-specific components in the sample have similar epitopes to capture fluorescently labeled antibodies as cNT-proBNP; 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 cNT-proBNP 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 cNT-proBNP 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 low temperature needs to be brought to the room temperature before opening to avoid moisture.
8. The operation shall be conducted away from vibration 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 cNT-proBNP in canine blood:

Detection range : 150- 6000 pmol/L

Reference: ≤ 800 pmol/L

Report result ($\mu\text{g/L}$)	Significance
≤ 800	Negative
> 800	Abnormal

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 $\pm 15.0\%$.
2. Inter-batch precision: The coefficient of variation (CV) is $\leq 15\%$ when the reference is determined by several kits of the same batches.
3. Batch-to-batch precision: The coefficient of variation (CV) is $\leq 20\%$ when the reference is determined by several kits of different batches.
4. The linearity of the dose-response curve: In the range of 150- 6000 pmol/L, the linear correlation coefficient of the dose-response curve is $R > 0.95$.
5. Interference test: At the test on following substances of specified concentration, an interference phenomenon is not found.

Bilirubin	400 $\mu\text{mol/L}$
Hemoglobin	5g/L
Triglyceride	15mmol/L

6.HOOK effect: When the concentration of cNT-proBNP is up to 100000 pmol/L, 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
LOT	Batch code	CE	CE Marking
	Keep away from sunlight		Keep dry
	Manufacturer	EU REP	Authorized Representative in European Community
	Caution		Do not use if package is damaged and consult instructions for use

Manufacture Information



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[Instructions Approval Date and Version number]

Version No.: 3.0

Effective Date: 2026.05.18

S6.10.99.031.A1

