Canine pancreatic-specific lipase (cPL) Test Kit Instructions for use

[Product Name]

Canine pancreatic-specific lipase (cPL)

[Packaging Specifications]

10 pieces/box

[Intended Use and Detection Principle]

This product is used for rapid detection of Canine pancreaticspecific lipase (cPL) concentration. The detection principle is to quantitatively determine the level of Canine pancreaticspecific lipase (cPL) by immuno assay analysis.

[Test Kit Composition]

Item	Quantity
Rapid test card	10 Test/box
Sample Diluent	10 tubes/box
Pipette tip	20 pcs/box

[Storage conditions and shelf life]

Shelf life: 24 months stored at 4~30°C.

After opening the aluminum foil pouch, use the test kit within 1 hour, at $18\sim28^{\circ}\text{C}$.

[Compatible instruments]

FLASHTEST Fluorescence quantitative analysis instrument

[Sample]

Serum or plasma

[Sample Handling]

If serum/plasma cannot be detected in time, it should be refrigerated at 2-8°C and tested within 3 days. If longer storage time is required, freeze at -20°C or below and complete the test within 3 months. The frozen sample should be restored to room temperature before use, and the sample should not be repeatedly frozen or thawed.

[Other lab instruments required]

Timer, pipette, centrifuge, etc

[Operations]

- 1. Tear open the aluminum foil pouch and take out the test card.
- 2. Pipette 50 μl serum/plasma sample into the sample diluent. Mix well.
- 3. After mixing the sample with diluent, add 100 μ l of diluent to the test card. The card should be placed on a leveled bench. Do not make bubbles when adding samples.
- 4. After adding the sample, incubate the test card at room temperature (18°C $\sim 28^{\circ}\text{C}$) for 10 minutes. Then run the test following instrument operational instructions.

[Interpretation of Test Results]

Detection range: 50-1000 ng/mL

Reference value:

Result Reading (ng/mL)	Interpretation
≤ 200	Normal
200 ~ 400	Suspected pancreatitis
> 400	Pancreatitis

The above results are for reference only. The final diagnosis requires a professional veterinarian to make a comprehensive judgment based on medical history, clinical symptoms, or other examinations.

[Explanation of Test Results]

 Insufficient sample or ineffective lateral flow over the detection line could cause abnormal C-line. At this time, the test card should be invalidated and a new card should be used for retesting. Due to technical reasons, operational errors, and other sample factors, errors in the test results may occur. If there are doubts about the test results, consider other diagnostic methods and make comprehensive disgnosis based on clinical symptoms.

[Limitations of testing methods]

- This reagent is only for testing dog serum, or plasma
 samples
- 2. The test results should be combined with other clinical and laboratory data. If the test results do not match the clinical evaluation, further examination is required.
- Potential cause of false positive: certain non-specific components in the blood have similar antigenic determinants to capture fluorescently labeled antibodies.
- 4. Potential cause of faise negative: some unknown components mask the antigenic determinant, making it unable to bind to antibodies; unstable antigens gradually degenerate over time and heat, thus cannot be recognized by antibodies; reagents and samples are not stored as required, resulting in abnormal test results.
- Other factors may also cause unexpected test results, including technical reasons, operational errors, and other sample factors.

[Precautions]

- This product is a disposable in vitro diagnostic reagent.

 Please do not reuse or use beyond the expiration time.
- 2. Please do not open the product before use. If the packaging is damaged, do not use the kit.
- 3. It is recommended to use fresh samples. If there is obvious hemolysis or blood clots in the sample that may interfere with the test or lead to incorrect results, do not use the kit.
- 4. Components across different test kits cannot be mixed in
- 5. The aluminum foil bag contains a desiccant and should not be taken orally. If the aluminum foil bag is leaking or damaged, do not use the kit.
- 6. Do not touch the test strip in the card.
- 7. Do not reuse the test kit and diluent.
- 8. This product is a screening kit. Any suspicious or positive results should be further confirmed by other methods.
- 9. All samples may be potentially infectious and should be
- handled and disposed in accordance with local regulations.

 10. Please read and follow the instructions carefully to ensure
- 10. Please read and follow the instructions carefully to ensure the accuracy of the test results.

[Production information]

See product packaging