

Clinical Efficacy Assessment of Vcheck fPL

Key words : Bionote, Vcheck, fPL, Pancreas-specific lipase, Pancreatitis

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Introduction

Pancreatitis is one of the most common disorders associated with pancreatic endocrine dysfunction in cats. Due to the difficulties in diagnosing pancreatitis, several tests are employed for more accurate, faster diagnosis.

Recently, the pancreatitis biomarker with the highest specificity in cats is feline pancreas-specific lipase (fPL). Measuring fPL and also performing abdominal ultrasonography are known to be useful for excluding other diseases with similar clinical symptoms to pancreatitis. While abdominal ultrasonography alone might have very high specificity for diagnosing pancreatitis, it has low sensitivity, and interpretation of the results is also highly affected by the examiner's experience. As a quantitative indicator, fPL measurement is a powerful method to make up for the limitations of abdominal ultrasonography.

In this study, we measured fPL using BIONOTE Vcheck, and IDEXX SPEC in cats who visited an animal hospital with suspected pancreatitis, and assessed the usefulness of Vcheck fPL test in clinical veterinary medicine.

Purpose

The objective of this study was to assess the clinical efficacy of the "Vcheck fPL test kit", which is a diagnostic test kit using a fluorescent immunoassay, which are developed and sold by BIONOTE Inc. For the efficacy assessment, we analyzed the sensitivity, specificity, and reference range, and compared the performance with products from competitors.

Materials and Methods

Control groups

At least 5 cats diagnosed as not having pancreatitis by a veterinarian (patients showing no effect on peak serum fPL)

Test groups

At least 5 cats diagnosed with pancreatitis by a veterinarian

Test items

- ① CBC
- ② Serum chemistry (Amylase, Lipase)
- ③ Ultrasonography
- ④ Clinical symptoms (compulsory)
- ⑤ Vcheck feline SAA (compulsory)
- ⑥ Vcheck fPL (compulsory)
- ⑦ IDEXX SPEC fPL (compulsory)
- ⑧ In order to exclude or confirm pancreatitis, Items ④~⑦ were compulsory. The definitive diagnosis for pancreatitis was made by a veterinarian after performing the necessary tests from among CBC, serum chemistry, and ultrasonography.

Results

See the following page.

Conclusion

This study indicates that Vcheck fPL has a high correlation with SPEC fPL used in IDEXX laboratories. Based on these results, the Vcheck fPL provides accurate and reliable test results in blood samples from cats in diagnosing pancreatitis.

Results

Correlation between BIONOTE Vcheck fPL and IDEXX SPEC fPL measurements

As shown in Fig. 1 below, Vcheck fPL and SPEC fPL showed a strong correlation, with $R^2 > 0.95$ ($y=0.87x+0.6$, $R^2=0.968$). Using a threshold value of 3.5 ng/mL, the interpretations of both tests were the same for all cats.

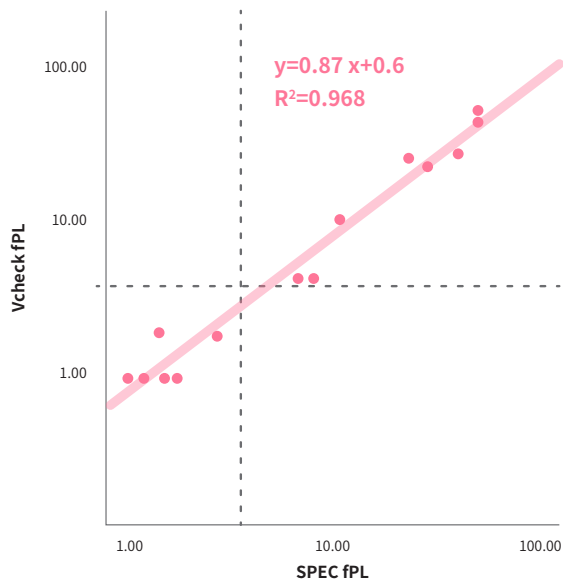


Figure 1.
Comparison of BIONOTE Vcheck fPL and IDEXX SPEC fPL measurements in cats

Comparison of BIONOTE Vcheck fPL and SPEC fPL measurements with definitive diagnosis

As shown in Fig. 2 below, using a threshold value of 3.5 ng/mL (Fig. 2, sparse dotted line), Vcheck fPL and SPEC fPL measurements were consistent with the pancreatitis diagnosis in all 10 cases.

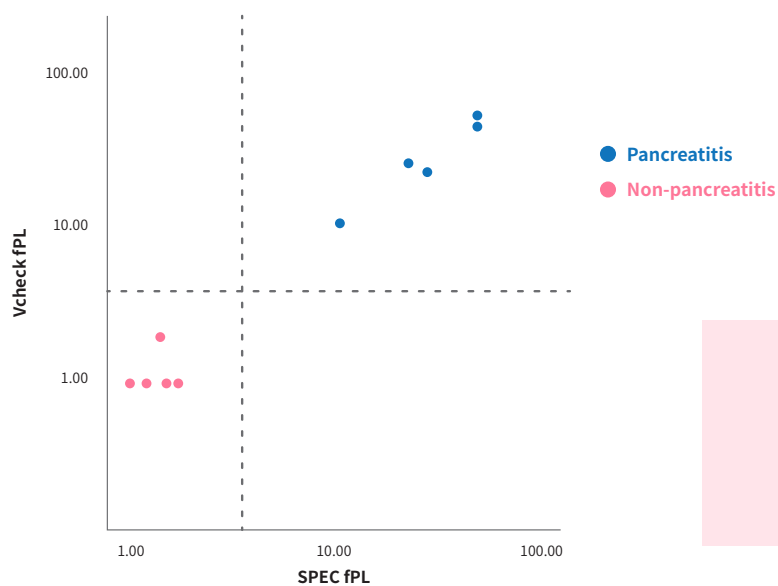


Figure 2.
Comparison of definitive diagnosis of pancreatitis with BIONOTE Vcheck fPL and SPEC fPL in patients visiting the hospital for the first time