

PRECISE DIAGNOSTICS
FOR IMPROVED CARE

VER.01



VCHECK PERFORMANCE EVALUATION.

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PRECISE DIAGNOSTICS FOR IMPROVED CARE

Vcheck is a multi-parametric fluorescent immunoassay analyzer providing rapid, accurate, and reliable results for quantitative, antibody titer, and infectious tests.

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Vcheck Canine Tnl

Comparison of 2 assays for measuring serum troponin I in dogs

INTRODUCTION

Troponin consists of 3 subunits (troponin I, T, and C) which together function as a molecular switch of cardiomyocyte contraction. Among them, cardiac Troponin I (Tnl) is a sensitive and specific circulating marker of cardiac injury for dogs. Vcheck Canine Tnl was developed to measure Tnl concentrations in canine serum samples, and this study reports the results of the comparison validation for this new method.

PURPOSE

The purpose of this study was to conduct a comparison of Tnl concentrations measured between Vcheck and Roche Elecsys, using canine serum.

MATERIALS AND METHODS

Total 156 samples were frozen immediately after serum collection in several animal hospitals in South Korea and shipped to the laboratory of Bionote (South Korea) on dry ice. The samples were analyzed with Vcheck Canine Tnl and Roche Elecsys Troponin I STAT according to each manufacturer's instructions. Pearson correlation coefficient was performed to measure the strength of the association between the two variables.

RESULTS

The test results for the correlation of the Tnl measurement between Vcheck and Roche Elecsys are shown in figure 1. A strong correlation (slope 0.9379, $R^2=0.9203$) was found between the two test methods.

CONCLUSION

Results of the Vcheck Canine Tnl test were comparable to those of the Roche Elecsys reference method, such that the Vcheck may be used as an alternative assay to evaluate serum troponin I concentration in canine patients for the screening of cardiac injury.

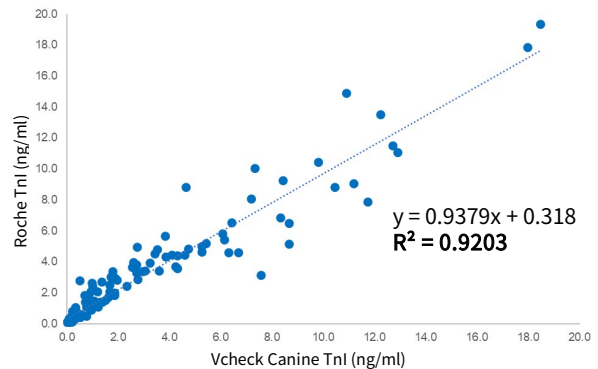


Figure 1. Correlation between the results of Vcheck and Roche Tnl in 156 canine samples

RAW DATA

Canine serum sample (n=156)

No.	Roche (ng/ml)	Vcheck (ng/ml)	No.	Roche (ng/ml)	Vcheck (ng/ml)	No.	Roche (ng/ml)	Vcheck (ng/ml)
1	<0.1	0.16	53	<0.1	0.03	105	2.71	1.34
2	<0.1	0.11	54	<0.1	0.01	106	2.80	0.50
3	<0.1	0.10	55	<0.1	0.01	107	2.84	1.95
4	<0.1	0.10	56	<0.1	0.08	108	2.87	2.77
5	<0.1	0.02	57	<0.1	0.01	109	2.96	1.87
6	<0.1	0.01	58	<0.1	0.01	110	3.03	1.70
7	<0.1	0.01	59	0.14	0.21	111	3.15	7.56
8	<0.1	0.01	60	0.16	0.12	112	3.29	2.71
9	<0.1	0.04	61	0.17	0.21	113	3.39	1.78
10	<0.1	0.02	62	0.18	0.11	114	3.4	2.94
11	<0.1	0.06	63	0.30	0.07	115	3.42	3.60
12	<0.1	0.04	64	0.34	0.10	116	3.43	3.03
13	<0.1	0.04	65	0.35	0.33	117	3.59	4.30
14	<0.1	0.02	66	0.38	0.29	118	3.67	2.55
15	<0.1	0.01	67	0.4	0.30	119	3.69	4.23
16	<0.1	0.01	68	0.40	0.11	120	3.81	2.71
17	<0.1	0.03	69	0.40	0.15	121	3.93	3.24
18	<0.1	0.04	70	0.41	0.53	122	3.98	2.59
19	<0.1	0.03	71	0.43	0.20	123	4.33	3.85
20	<0.1	0.02	72	0.45	0.21	124	4.43	4.31
21	<0.1	0.01	73	0.5	0.76	125	4.44	4.58
22	<0.1	0.04	74	0.6	0.58	126	4.46	4.10
23	<0.1	0.05	75	0.632	0.21	127	4.51	3.43
24	<0.1	0.12	76	0.67	0.45	128	4.60	6.29
25	<0.1	0.01	77	0.74	0.26	129	4.62	6.69
26	<0.1	0.01	78	0.81	0.21	130	4.63	5.27
27	<0.1	0.08	79	0.90	0.95	131	4.79	3.53
28	<0.1	0.01	80	1.05	0.33	132	4.84	4.72
29	<0.1	0.02	81	1.05	0.33	133	4.96	2.74
30	<0.1	0.06	82	1.09	0.77	134	5.00	5.25
31	<0.1	0.03	83	1.1	1.22	135	5.15	8.65
32	<0.1	0.01	84	1.3	1.13	136	5.20	5.42
33	<0.1	0.11	85	1.33	1.20	137	5.45	6.14
34	<0.1	0.09	86	1.40	0.70	138	5.69	3.83
35	<0.1	0.02	87	1.42	1.37	139	5.81	6.07
36	<0.1	0.08	88	1.42	0.91	140	6.48	8.65
37	<0.1	0.01	89	1.42	1.29	141	6.53	6.43
38	<0.1	0.02	90	1.44	0.96	142	6.86	8.33
39	<0.1	0.01	91	1.49	1.05	143	7.87	11.72
40	<0.1	0.01	92	1.54	1.49	144	8.09	7.17
41	<0.1	0.01	93	1.74	1.63	145	8.83	4.64
42	<0.1	0.11	94	1.76	0.82	146	8.84	10.45
43	<0.1	0.02	95	1.86	0.69	147	9.06	11.17
44	<0.1	0.01	96	1.86	1.85	148	9.24	8.42
45	<0.1	0.01	97	1.99	1.86	149	10.03	7.33
46	<0.1	0.01	98	2.10	1.19	150	10.45	9.81
47	<0.1	0.01	99	2.10	0.92	151	11.08	12.89
48	<0.1	0.11	100	2.10	1.66	152	11.5	12.71
49	<0.1	0.02	101	2.42	2.32	153	13.51	12.23
50	<0.1	0.07	102	2.43	1.00	154	14.90	10.88
51	<0.1	0.01	103	2.51	1.67	155	17.84	17.97
52	<0.1	0.08	104	2.65	0.97	156	19.37	18.47

Vcheck Canine NT-proBNP

Comparison of 2 assays for measuring serum N-terminal pro-B-type natriuretic peptide (NT-proBNP) in dogs

INTRODUCTION

Pro-hormone (proBNP) is produced by cardiac muscle cells and increases due to increased myocardial wall stress. Upon release into the blood, it is cleaved into B-type natriuretic peptide (BNP) and N-terminal pro-B-type natriuretic peptide (NT-proBNP). Due to its longer half-life and stability, NT-proBNP is better suited as a diagnostic biomarker for the diagnosis of heart diseases in dogs.

There were several limitations associated with the need to maintain sample stability. Vcheck Canine NT-proBNP was developed to address these limitations, and this study reports the results of the comparison validation for this new method.

PURPOSE

The purpose of this study was to conduct a comparison of NT-proBNP concentrations, measured between Cardiopet® - a previously validated enzyme-linked immunosorbent assay - and Vcheck, using canine serum.

MATERIALS AND METHODS

Total 66 canine serum samples were analyzed with Vcheck Canine NT-proBNP (Bionote) according to the manufacturer's instructions. The remainder of the samples were frozen immediately and shipped to the IDEXX Laboratories (South Korea) on dry ice for Cardiopet® proBNP testing. Pearson correlation coefficient was performed to measure the strength of the association between the two variables.

RESULTS

The test results for the correlation of the NT-proBNP measurement between Vcheck and Cardiopet® are shown in figure 1. A strong correlation (slope 0.9954, $R^2=0.9736$) was found between the two test methods.

CONCLUSION

Results of this study have validated the Vcheck Canine NT-proBNP test to be an accurate and

precise measuring tool for NT-proBNP in canine patients. In addition, this method can also be performed immediately after sample collection using serum without worrying about the sample stability.

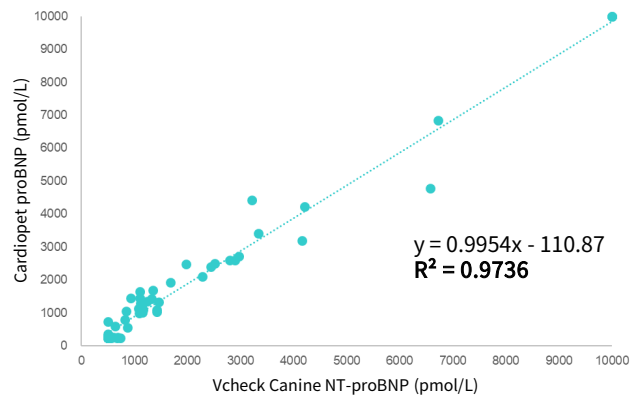


Figure 1. Correlation between the results of Vcheck Canine NT-proBNP and Cardiopet® proBNP in 66 canine serum samples

RAW DATA

No.	Cardiopet (pmol/L)	Vcheck (pmol/L)	No.	Cardiopet (pmol/L)	Vcheck (pmol/L)
1	<250	<500	34	1013	1147.1
2	<250	<500	35	1029	1420.7
3	<250	<500	36	1054	839.8
4	<250	<500	37	1066	1113.4
5	<250	<500	38	1093	1421.6
6	<250	<500	39	1095	1162.9
7	<250	<500	40	1141	1079.0
8	<250	<500	41	1219	1137.5
9	<250	<500	42	1289	1115.1
10	<250	<500	43	1340	1461.0
11	<250	669.4	44	1357	1239.2
12	<250	<500	45	1428	1317.9
13	<250	<500	46	1447	931.2
14	<250	518.9	47	1453	1100.9
15	<250	563.9	48	1650	1099.5
16	<250	729.8	49	1685	1342.1
17	<250	<500	50	1921	1678.4
18	<250	<500	51	2096	2284.8
19	<250	<500	52	2401	2444.9
20	<250	<500	53	2480	1977.6
21	256	606.3	54	2506	2508.3
22	261	680.8	55	2598	2797.3
23	283	<500	56	2604	2887.9
24	284	545.7	57	2712	2964.0
25	289	<500	58	3189	4161.7
26	296	<500	59	3420	3338.9
27	305	<500	60	4232	4211.2
28	357	<500	61	4426	3217.6
29	554	867.7	62	4779	6575.5
30	599	641.4	63	6840	6726.8
31	742	<500	64	>10000	>10000
32	801	816.4	65	>10000	>10000
33	998	1089.2	66	>10000	>10000

Vcheck Canine NT-proBNP

Veterinary Application of Bionote's N-Terminal pro-Brain Natriuretic Peptide (NT-proBNP) Sample Handling and Significance of Temperature Control

Background¹

Brain natriuretic peptide (BNP) is a 32-amino acid cardiac natriuretic peptide hormone originally isolated from porcine brain tissue. The biologically active BNP and the prohormone, NT proBNP (76 amino acids) found in the peripheral blood are produced predominately by cardiac myocytes and fibroblasts. The main stimulus for production of the natriuretic peptides is myocardial stretch or stretch of the heart's walls due to increased volume and pressure. BNP binds to receptors in other organs such as the kidney, stimulates increased intracellular cGMP production, and induces diuresis, vasodilation, inhibits renin and aldosterone production, and inhibits cardiac and vascular myocyte growth, and possibly inhibits fibroblast proliferation.

In contrast to atrial NP, which originates mainly in the atrial tissue, NT-proBNP/BNP are produced mainly in ventricular tissues, though there is an atrial component.

NT-proBNP production is significantly upregulated in cardiac failure and locally in the area of myocardial infarction.

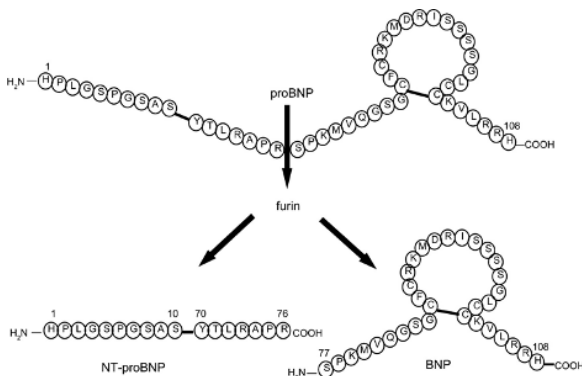


Figure 1: Production of NT-proBNP and BNP

Preanalytical Considerations - Sampling, Transport and Storage

The very short half-life of canine BNP (as little as 90 seconds) which enables quickly-tailored physiologic adjustments in the body, makes the active compound unusable as a diagnostic. NT-proBNP in dogs does have a longer half-life; however, unlike human NT-proBNP, the half-life of this compound at room temperature can be as little as 120 minutes. This means that over the

course of an afternoon -if left at room temperature - the sampling could have 25% of the original concentration. While the exact measured concentration decrease may change based on the targeted epitope in the assay, and the amount of degradation varies from individual sample- to-sample, a significantly decreased measured concentration is expected within 24 hours in samples at both refrigerated and room temperature based on previous studies in dogs.^{2,3}

Refrigeration

Using this assay, an average 20% loss from original concentration was documented in a 14-hour time period when samples were stored at 4°C. Therefore, 24-hour refrigeration will result in non-diagnostic samples. This is consistent with what has been previously found in dogs.³

SAMPLE HANDLING RECOMMENDATIONS: Serum should be separated and analyzed within 1 hour of collection. Serum samples must be frozen, not refrigerated, if the assay is to be performed more than 6 hours after sampling.

Imprecision Study

Imprecision varies across concentrations. In-clinic measured imprecision using 20 replicates:

A replicate study of a sample of approximately 350 pmol/L generated a result of 611 pmol/L.

Approximate Concentration (pmol/L)	Coefficient of Variation (CV%)
700	20
1900	12
4000	9

Precision varies across concentration of NT-proBNP

Linear Range

The manufacturer listed range is from 500 to 10,000pmol/L.

Based on imprecision studies, the recommended linear range is from 700 to 10,000pmol/L.⁴ (This change does not affect clinical interpretation.)

Accuracy

When using dry ice to ship frozen samples to a reference lab, instrument comparison of the Bionote in-clinic analysis to the reference lab analysis showed excellent correlation, with a slope of 1 and a mild positive bias of 63 pmol/L ($r=.94$, $R^2=0.90$)

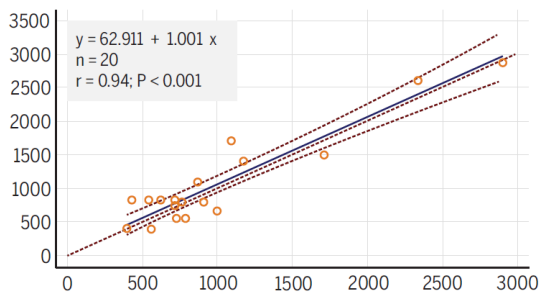


Figure 2

Preanalytical Concerns

When samples were treated in a real-world, in-clinic setting (shipped with couriers and analyzed as recommended by the manufacturer), the R^2 falls to 0.85 and the positive bias increases to >750 pmol/L. This positive bias of the in-house assay in comparison to the reference laboratory is consistent with sample degradation (see Preanalytical Error for explanation). When paired sample results are compared, these discrepancies are clinically significant in approximately 30% of the samples, with a resultant difference in diagnosis.

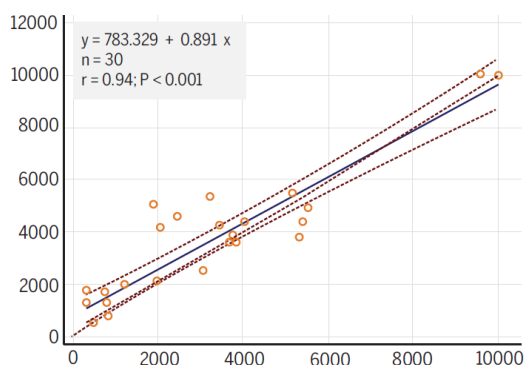


Figure 3

Interferents (Analytical Specificity)

It was confirmed that Vcheck Canine NT-proBNP did not show interference reactions with intralipid of 1200 mg/dL or less, bilirubin of 5 mg/dL or less, vitamin C of 1000 mg/dL or less, and hemoglobin of 37.5 mg/dL or less.

Moderately to severely hemolyzed samples (red samples) should not be used for testing.

Interfering Substance	Conc. (mg/dL)	Interference
Hemoglobin	≤ 37.5	None
Intralipid	≤ 1200	None
Bilirubin	≤ 5	None
Vitamin C	≤ 1000	None

References

Bionote study led by Dr. Kendal E. Harr DVM, MS, DACVP

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Vcheck Feline NT-proBNP

Evaluation of correlation between Vcheck and company 'I' laboratories for feline NT-proBNP

INTRODUCTION

N-terminal pro-B type natriuretic peptide (NT-proBNP) is cleaved from BNP which is produced by the muscle cells of the heart and increases with excessive stretching of the cells. NT-proBNP concentration reflects the degree of cardiac activation secondary to stimulus, such as stretching, allowing this marker to be used to assess the magnitude of cardiac muscle stretching.

NT-proBNP is a valuable biomarker for differentiating cardiac and respiratory causes of dyspnea and can be used for screening occult heart disease in asymptomatic cats.

PURPOSE

The objective of this study was to conduct a comparison of Feline NT-proBNP concentrations between the Vcheck and the ELISA method used in 'I' laboratories, in order to ensure that there are no significant differences between the results.

MATERIALS AND METHODS

A total of 37 feline serum samples were analyzed with Vcheck V200 according to the manufacturer's instructions and also analyzed with an ELISA method by a laboratory for comparison.

Reference method

- Device: an ELISA method by 'I' laboratories
- Reagent: Cardiopet proBNP

Method to validate

- Device: Vcheck V200
- Reagent: Feline NT-proBNP

RESULTS

The test results for the correlation of feline NT-proBNP between Bionote Vcheck and an ELISA method at a laboratory are shown in Figure 1.

CONCLUSION

This study indicates that Vcheck Feline NT-proBNP has a high correlation with an ELISA method used in company 'I' laboratories (Feline NT-proBNP; $R^2=0.9645$).

Based on these results, the Vcheck Feline NT-proBNP provides accurate and reliable test results in serum samples from cats, as compared to an ELISA reference method.

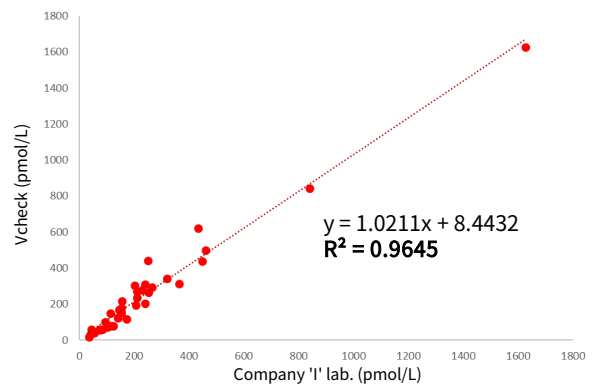


Figure 1. Correlation between the results of Vcheck Feline NT-proBNP and an ELISA method from 'I' laboratories in feline serum samples (N=37)

REFERENCE

1. Mark Oyama. Cardiac Blood Tests in Cats: Another Tool for Detection of Heart Disease. Today's Veterinary Practice. September/October 2011
2. Connolly DJ, Soares Magalhaes RJ, Fuentes VL, et al. Assessment of the diagnostic accuracy of circulating natriuretic peptide concentrations to distinguish between cats with cardiac and non-cardiac causes of respiratory distress. J Vet Cardiol 2009;11(Suppl 1):S41-S50

RAW DATA

Feline serum sample (n=37)

No.	IDEXX (pmol/L)	Vcheck (pmol/L)	No.	IDEXX (pmol/L)	Vcheck (pmol/L)
1	36	<50	20	172	117
2	40	<50	21	203	302.1
3	44	58.9	22	207	193.7
4	55	<50	23	210	236.3
5	73	57.6	24	210	270.3
6	77	54.5	25	230	278.3
7	84	59.3	26	240	202.9
8	95	100.9	27	241	310.1
9	104	83.4	28	250	440
10	104	71.6	29	252	265.2
11	113	150	30	265	294.9
12	118	79	31	320	342.8
13	125	79.3	32	364	312.9
14	141	123	33	435	622.5
15	142	124.7	34	448	437.4
16	146	168.1	35	461	497.9
17	153	151	36	841	843.1
18	155	178.4	37	1628	1627.4
19	157	217.1			

Vcheck D-dimer

Vcheck D-dimer test kit performance comparison and clinical efficacy evaluation

Evaluated by 'H' Referral Animal Hospital Small Animal Clinical Research in South Korea

INTRODUCTION

D-dimers result from the degradation of cross-linked fibrin, and in contrast to other degradation products, are specific for active coagulation and fibrinolysis. Several preliminary veterinary studies have shown promise for using D-dimer to screen for DIC and thromboembolic disease prior to overt DIC. Likewise, D-dimer is highly sensitive for the diagnosis of Pulmonary Thromboembolism (PTE). A sensitive D-dimer assay may essentially rule out thromboembolism if negative.

PURPOSE

The objective of this study was to evaluate the correlation between Vcheck D-dimer and commercially available D-dimer measurement methods (NycoCard™ or Mindray™ (BS390)), and to evaluate the clinical efficacy in patients with heart valve disease, tumor, systemic inflammation, hormonal disease, immune-mediated disease, protein-losing enteropathy and patients with suspected symptoms of thrombosis.

MATERIALS AND METHODS

Material

- Blood samples were collected from 50 patients with heart valve disease, tumor, systemic inflammation, hormonal disease, immune-mediated disease, and protein-losing enteropathy, and patients with suspected symptoms of thrombosis.
- The veterinarian determined whether the D-dimer test was necessary, based on the patient's comprehensive medical history, physical exam and labwork (CBC, profile, PT, aPTT).

Method

- Tests were performed using Vcheck D-dimer and another commercial test kit (NycoCard™) according to the manufacturer's instruction. If there was a difference between the two test results, an additional D-dimer test (Mindray™ (BS390)) was conducted (Table 1).

Table 1. Normal range of the D-dimer tests for different analyzers

Equipment or test reagents	Normal range
Vcheck D-dimer	< 0.3 µg/ml
NycoCard™	< 0.3 µg/ml
Mindray™ (BS390)	< 0.5 µg/ml

RESULTS

- In a total of 49 samples (one sample was excluded due to test error), Vcheck and NycoCard™ showed 93.9% (46 cases) of coincidence, and showed a correlation of $R^2 = 0.854$ (Figure 1).
- There were 12 samples (24.5%) with a difference of 0.2 µg/ml or more, or a difference in interpretation. A total of 3 samples produced inconsistencies in the interpretation of the results, two of which (sample no. 6 and 15) found that normal levels of Vcheck were more helpful for diagnosis, and in the remaining other case (sample no. 33), both results were considered possible (Table 2).

D-dimer results from Mindray (BS390) in samples with inconsistent results

- The comparison using Mindray™ was conducted on four samples (No.36, 44, 47, 48), and it was confirmed that all four cases were abnormal and the same analysis was performed on all three analyzers. Mindray™ showed the highest measurements on three samples (No.36, 44, 47), while Vcheck result was the highest on No.48 (The patient died the next day after the last visit).
- Considering the normal range of Mindray™ (< 0.5 µg/ml), the measured value is expected to show the highest tendency, but the highest measured value of Vcheck on No.48 can be interpreted to be the most consistent with the progression of the patient's symptoms.

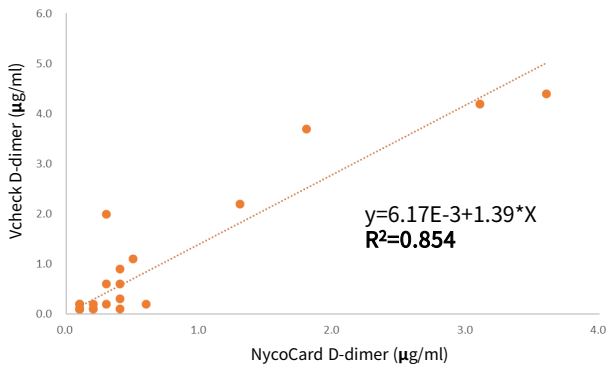


Figure 1. Correlation of Vcheck D-dimer with NycoCard™ in canine plasma samples (N=49)

CONCLUSION

There was a high correlation (93.9%, $R^2=0.854$) of D-dimer between Vcheck and NycoCard™.

Considering the comprehensive test results and the condition of the patients, Vcheck D-dimer results were considered to be clinically more useful for diagnosing and predicting prognosis.

Rather than relying on absolute values for measured values above the normal range, it is considered to be a more important criterion for determining the reliability of an analyzer by looking at whether the measured values decrease as the symptoms of patients improve.

REFERENCE

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2. Nelson OL. Use of the D-dimer Assay for Diagnosing Thromboembolic Disease in the Dog. *J Am Anim Hosp Assoc* 2005;41:145-149

Table 2. Clinical cases showing a difference of 0.2 µg/ml or more, or a difference in interpretation, which Vcheck D-dimer results are considered to be clinically more useful

Sample No.	Main Symptom	Diagnosis	D-dimer (µg/ml)			The reason the Vcheck D-dimer results are considered to be clinically more useful
			Vcheck	NycoCard™	Mindray™	
6	cough	normal	< 0.1	0.4	Not tested	Considering the comprehensive test results and the condition of the patients, it is considered that the result within normal range was more helpful for the diagnosis.
12	ascites, dyspnea	cardiac tamponade	0.4	3.2	Not tested	Since the patient is expected to have a rise in D-dimer, both 3.2 and 0.4 are possible, but a value of 3.2 is thought to be an error as the laboratory reported clots were found in the sample.
15	weight loss, lethargy	pancreatitis, renal failure	0.2	0.6	Not tested	Although the patient had gastroenteritis and pancreatitis, the CRP was within the normal range and there were no significant intestinal symptoms. The D-dimer normal result was considered to be more useful for clinical diagnosis.
26	lethargy, anorexia	bacterial endocarditis, non-regenerative anemia	0.6	0.3	Not tested	Considering the stage of SIRS progression in this patient, a high D-dimer level was considered to be helpful in clinical diagnosis and treatment.
48	liver hypertrophy, anemia	gall bladder sludge, hepatitis, renal cyst	2.0	0.3	1.94	In this case, the patient died a day after visiting. Considering this outcome, the higher D-dimer is considered to be helpful for diagnosis and treatment.

INTRODUCTION

Canine filariasis is a prominent mosquito-borne disease which is caused by several species of filarial worms, including *Dirofilaria immitis*. The pathophysiological response to infection is mainly due to the filaria lifecycle. New laboratory detection methods to assess the pathological alterations characteristic of filariasis are needed urgently.

PURPOSE

Serum protein profiles and C-reactive protein (CRP) are used widely to diagnose several animal diseases. The aim of this study was to determine and to compare the serum protein profiles and CRP level in dogs infected with *D. immitis* or *Brugia pahangi*.

MATERIALS AND METHODS

Blood samples were collected from 980 dogs presenting at animal hospitals and veterinary clinics. All samples were tested to determine the presence of microfilaria using buffy coat blood smears and staining with Wright–Giemsa. In positive samples, proteins were separated by agarose gel electrophoresis to examine the serum protein profiles and CRP concentrations were determined using the Vcheck CRP assay (Bionote).

RESULTS

In canine filariasis, albumin levels and A/G ratios were significantly low, and total protein, β 2 globulin, and γ globulin levels were significantly elevated. The average CRP concentrations in dogs infected with *D. immitis* or *B. pahangi* were 69.6 (13.6–116.9) and 12.9 (< 10–31) mg/L, respectively (n=6, both). The CRP concentration in the dog infected with both parasites was > 200 mg/L (n=1).

CONCLUSION

The serum protein profiles and CRP concentrations in canine filariasis can reflect the health status of infected dogs. The CRP assay can be used as a useful marker in dogs infected with *D. immitis*, as it is elevated because of the inflammation involved in the pathogenesis.

Table 1. Serum protein concentrations in canine filariasis

Variable (g/dL)	D. immitis positive (mean \pm SD, n=24)	B. pahangi positive (mean \pm SD, n=15)	Reference range
Total protein	9.22 \pm 2.40	8.50 \pm 1.75	5.40–7.10
Albumin	2.07 \pm 0.70	2.28 \pm 0.50	2.60–3.30
Alpha-1	0.34 \pm 0.17	0.43 \pm 0.18	0.20–0.50
Alpha-2	0.66 \pm 0.55	0.52 \pm 0.45	0.30–1.10
Beta-1	1.15 \pm 0.53	0.87 \pm 0.46	0.70–1.30
Beta-2	2.23 \pm 1.02	1.79 \pm 0.06	0.60–1.40
Gamma	2.77 \pm 1.84	2.63 \pm 1.17	0.90–2.20
A/G ratio	0.33 \pm 0.12	0.41 \pm 0.15	0.59–1.11

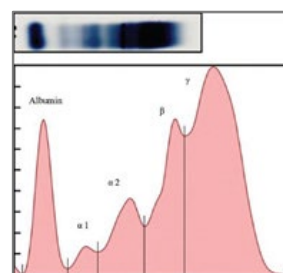
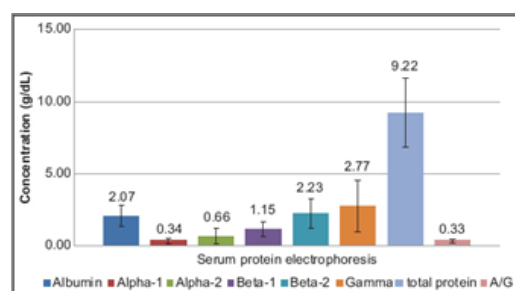


Figure 1-2. The serum protein concentrations and electrophoretogram in dogs infected with *D. immitis*

Vcheck CRP

Analytical performance of a portable POCT (BIONOTE Vcheck) for canine CRP

INTRODUCTION

BIONOTE V100 is a newly introduced POCT for animal hormones and metabolites. It can be used to measure blood concentrations of different substances by detecting emission lights from latex beads, gold substrates, or fluorescent particles. BioNote currently have BIONOTE Vcheck Canine CRP to measure canine serum CRP concentration with BIONOTE V100.

PURPOSE

The purpose of this study is to validate the analytical performance of BIONOTE V100 and BIONOTE Vcheck Canine CRP using canine serum samples and to compare its performance with a reference analysis from 'B' company.

MATERIALS AND METHODS

Serum CRP concentrations of a hundred dogs were measured with BIONOTE V100 and a product from 'B' company at the same time, and the correlation of the results between the two analysis was assessed. Also, coefficient value to confirm the reproducibility of BIONOTE V100 was assessed using dogs' serum samples with different CRP concentrations, and machine's linearity was evaluated by comparing the actual value and the measured value of serially diluted dog serum samples.

RESULTS

Correlation

For the Correlation between BIONOTE V100 and a product from 'B' company, the coefficient of determination value was 0.963. ($R^2=0.963$) and the linear regression function was calculated as $y = 0.9764x + 8.0667$. (Figure 1)

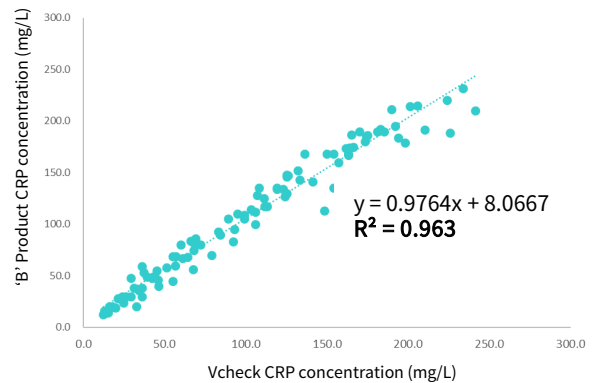


Figure 1. Correlation between BIONOTE Vcheck Canine CRP and ELISA from 'B' company (mg/L)

Reproducibility

Reproducibility of BIONOTE Vcheck Canine CRP was evaluated using dog sera of three different CRP concentrations; high (105.9 mg/L), medium (50.9 mg/L), and low (12.7 mg/L)

Table 1. Coefficient Values (CV) for each canine serum sample

High (105.9 mg/L)	Medium (50.9 mg/L)	Low (12.7 mg/L)
6.01%	6.23%	5.03%

Linearity

A two fold serial dilution was done with dog serum sample having 108 mg/L of CRP. Subsequently, actual CRP concentration and the CRP concentration measured by BIONOTE Vcheck Canine CRP was compared. As a result, the coefficient of determination value and the linear regression function is calculated as 0.9999 ($R^2=0.9999$) and $y = 1.0001x + 0.069$ respectively. (Figure 2)

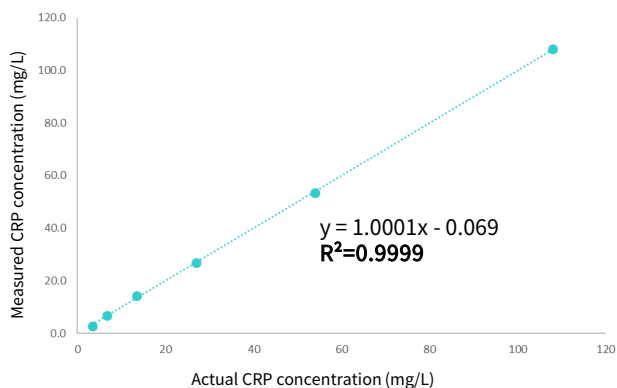


Figure 2. Comparison between actual CRP concentration and measured CRP concentration

RAW DATA

Canine serum sample (n=100)

No.	Vcheck (mg/L)	BD ELISA (mg/L)	No.	Vcheck (mg/L)	BD ELISA (mg/L)
1	12.1	12.7	51	99	109
2	13	16	52	103	114
3	13.2	13.7	53	106	112
4	15	14	54	106	100
5	16	20	55	107	128
6	16.7	19.3	56	108	135
7	17.6	20.0	57	111	125
8	19.7	19.3	58	111.5	117.0
9	21	28	59	113	117
10	23.7	30.0	60	119	134
11	24.5	23.9	61	119	135
12	26	30	62	123	134
13	29	48	63	124	127
14	29.3	30	64	125	148
15	31	38	65	125	130
16	32.6	20.4	66	125	146
17	34	36	67	126	147
18	36	38	68	132	152
19	36	30	69	133	143
20	36	59	70	136	168
21	36.9	53.4	71	141	141
22	39	49	72	148.3	112.8
23	42	48	73	150	168
24	43	49	74	154	135
25	44	49	75	154	168
26	45	55	76	157	160
27	46	46	77	161.8	173.6
28	46.4	40.1	78	163	167
29	51.1	58.0	79	163	168
30	55	45	80	164	174
31	55	69	81	165	187
32	56.4	60.0	82	166	175
33	57	69	83	170	190
34	60	80	84	173.4	180
35	61	67	85	174.1	185.0
36	64	68	86	175	186
37	66	84	87	181	190
38	67.4	56.2	88	183	192
39	68	75	89	185	190
40	68	82	90	189.6	211.2
41	69	86	91	192	195
42	72	80	92	194	184
43	78.7	70	93	198.2	178.7
44	83.0	93.0	94	>200	214.0
45	84	90	95	>200	215.0
46	89.1	105.5	96	>200	191.5
47	92	83	97	>200	220.0
48	93	95	98	>200	188.6
49	95	110	99	>200	231.6
50	99	105	100	>200	210

Vcheck SAA

Analytical performance of a portable POCT Bionote Vcheck for Feline SAA (Serum Amyloid A)

INTRODUCTION

BIONOTE V100 is a newly introduced POCT for animal hormones and metabolites. It can be used to measure blood concentrations of different substances by detecting emission lights from latex beads, gold substrates, or fluorescent particles. BioNote currently have BIONOTE Vcheck Feline SAA to measure feline serum amyloid A concentration with BIONOTE V100.

PURPOSE

The purpose of this study is to validate the analytical performance of BIONOTE V100 and BIONOTE Vcheck Feline SAA using feline serum samples and to compare its performance with a reference analysis of 'I' company.

MATERIALS AND METHODS

Serum amyloid A concentrations of a hundred and thirty five cats were measured with BIONOTE V100 and a product from 'I' company simultaneously, and the correlation of the results between the two experiments were assessed. Also, coefficient values to confirm the reproducibility of BIONOTE V100 were assessed using cats' serum samples with different SAA concentration. Lastly, product's linearity was evaluated by comparing the calculated value and the measured value of serially diluted cat serum samples.

RESULTS

Correlation

For the Correlation between BIONOTE V100 and the product from 'I' company, the coefficient of determination value was 0.9702. ($R^2 = 0.9702$) and the linear regression function was calculated as $y = 0.9468x + 3.6278$. (Figure 1)

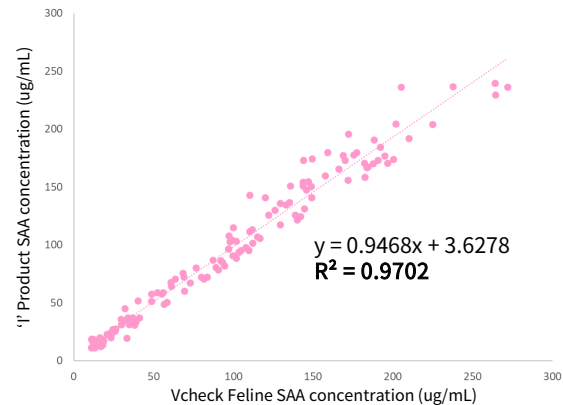


Figure 1. Correlation between BIONOTE Vcheck Feline SAA and ELISA from 'I' company (ug/mL)

Reproducibility

Reproducibility of BIONOTE Vcheck Feline SAA was evaluated using cat sera of three different SAA concentrations; high (112.9 ug/mL), medium (57.9 ug/mL), and low (12.7 ug/mL).

Table 1. Coefficient Values (CV) for three feline serum samples

High (112.9 mg/L)	Medium (57.9 mg/L)	Low (12.7 mg/L)
8.73%	5.91%	7.43%

Linearity

A two fold serial dilution was done with cat serum sample having 223 ug/ml of SAA. Subsequently, actual SAA concentration and the SAA concentration measured by BIONOTE Vcheck Feline SAA was compared. As a result, the coefficient of determination value and the linear regression function is calculated as 0.9996 ($R^2 = 0.9996$) and $y = 1.0131x + 1.6474$ respectively. (Figure 2)

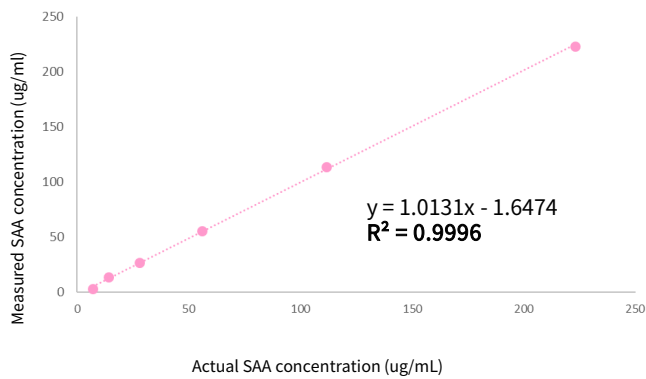


Figure 2. Comparison between actual SAA concentrations and measured SAA concentrations

RAW DATA

Feline serum sample (n=135)

No.	Vcheck (ug/ml)	ELISA (ug/ml)	No.	Vcheck (ug/ml)	ELISA (ug/ml)	No.	Vcheck (ug/ml)	ELISA (ug/ml)
1	11.0	18.9	46	52.1	58.9	91	129.1	135.9
2	11.0	11.2	47	55.0	57.9	92	129.1	117.4
3	11.1	11.7	48	55.9	58.8	93	132.8	134.7
4	11.2	17.4	49	56.4	49	94	135.0	136.9
5	11.2	11.8	50	58.3	50.7	95	135.7	150.8
6	12.0	18.9	51	60.8	67.6	96	138.7	126.1
7	13.1	14.5	52	61.1	64.3	97	139.8	121.6
8	13.1	11.4	53	63.5	70.6	98	142.0	124.5
9	14.6	16.2	54	68.3	75.9	99	143.5	154.5
10	15.8	16.6	55	68.9	72.5	100	143.5	151
11	16.2	19.9	56	69.1	60.1	101	143.7	173.3
12	16.8	12.4	57	73.0	67.5	102	144.5	131.4
13	17.5	15.9	58	76.5	80.5	103	145.6	147.7
14	18	13.7	59	79.8	72.5	104	146.9	154.6
15	18.1	18.1	60	81.4	70.8	105	148.6	150.7
16	18.7	17	61	83.4	72.5	106	149.0	140.8
17	20.7	23	62	87.2	87	107	149.1	174.6
18	21.6	22.7	63	89.0	80.9	108	157.5	159.7
19	22.5	23.7	64	90.5	78.7	109	158.9	180
20	23.2	20.2	65	92.0	86.4	110	166.0	165.7
21	23.4	23.7	66	93.2	84.7	111	168.5	177.4
22	24.5	24.8	67	94.4	82.1	112	170.0	173.3
23	24.5	27.2	68	96.9	96.7	113	171.7	156.1
24	25.5	25.9	69	96.9	96.7	114	172.0	195.6
25	25.8	26	70	97.1	107.9	115	175.4	177.9
26	26.0	27.4	71	97.8	102.9	116	177.2	179.7
27	29.4	36	72	99.1	104.3	117	182.0	170.6
28	29.9	31.5	73	99.7	90.6	118	182.2	158.4
29	29.9	31.5	74	99.8	115	119	183.4	166.7
30	30.4	33.8	75	101.8	103.2	120	184.3	167.5
31	32.0	45	76	101.8	88.5	121	187.3	170.3
32	33.0	19.8	77	103.2	93.8	122	187.9	190.6
33	33.7	37.4	78	104.8	95.3	123	190.4	173.1
34	34.0	34.5	79	107.7	97.9	124	192.0	184.6
35	34.3	34.2	80	109.5	95.2	125	194.6	176.9
36	34.5	31.4	81	110.0	142.9	126	196.4	170.8
37	36.8	36.7	82	110.0	111.6	127	>200	174.2
38	36.8	37.3	83	110.0	111.6	128	>200	204.7
39	38.0	30.9	84	111.7	113.3	129	>200	236.2
40	38.1	33.1	85	112.0	101.8	130	>200	192
41	39.0	33.9	86	115.0	107	131	>200	204.2
42	40.0	51.9	87	116.4	105.8	132	>200	236.9
43	41.1	37.4	88	120.0	141	133	>200	239.8
44	48.7	57.9	89	122.0	126.1	134	>200	229.6
45	48.7	51.3	90	126.0	130	135	>200	236.4

Vcheck cPL

Evaluation of correlation between the BioNote Vcheck and a commercial ELISA for Canine cPL

INTRODUCTION

Acute pancreatitis (AP) in dogs is a potentially reversible condition, but in severe forms it can cause systemic and local complications.¹ But diagnosis of AP can be difficult because of non-specific clinical signs.² The cPL (canine pancreas-specific lipase) is lipase enzyme that originate specifically in the pancreas. The cPL assay is the most sensitive non-invasive tests for the diagnosis of AP.

The BioNote Vcheck cPL is an in vitro fluorescent immunoassay test kit for the quantitative measurement of cPL concentration in canine serum. Since the kit provides quantitative measurement of cPL levels, BioNote Vcheck cPL can be tested to diagnose pancreatitis.

PURPOSE

This is to evaluate correlation between Vcheck and IDEXX SPEC cPL that provides the same diagnostic benefits as the original canine pancreatic lipase immunoreactivity (cPLI), in terms of measuring concentrations of canine serum cPL.

MATERIALS AND METHODS

The BioNote Vcheck cPL was carried out in accordance with the protocol provided by BioNote. The sensitivity and specificity of Vcheck cPL was evaluated using the test results from BioNote laboratory.

Fifty canine sera obtained from multiple animal hospitals in the Republic Korea were tested.

RESULTS

The test results for the 50 experimental canine sera were described in figure 1 and table 1. These samples had various cPL concentrations. 42 samples were above the normal range for the cPL.

We used the IDEXX SPEC cPL ELISA results for these sera as a gold standard test. The diagnostic sensitivity for the BioNote Vcheck cPL was 97.6% and the diagnostic specificity was 100%.

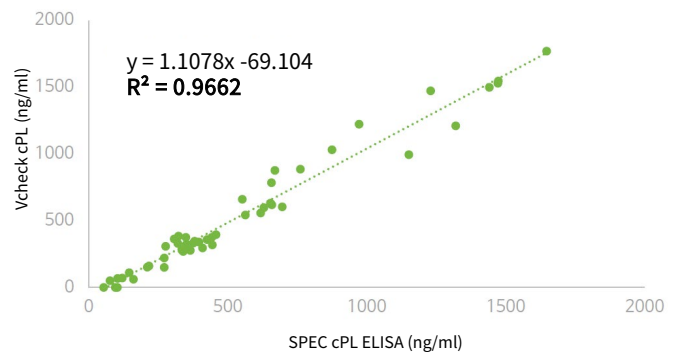


Figure 1. Correlation between Vcheck cPL and SPEC cPL ELISA (n=50)

Table 1. Correlation between normal and abnormal (n=50)

		Vcheck cPL	Spec cPL ELISA
< 200 ng/ml	Normal	9	8
200~400 ng/ml	Elevated	19	18
> 400 ng/ml	Consistent with pancreatitis	22	24

CONCLUSION

There were strong agreement between the two assays (IDEXX SPEC ELISA and the BioNote Vcheck) for cPL, which was 96%.

REFERENCE

1. Mansfield, C. (2012). Acute pancreatitis in dogs: advances in understanding, diagnostics, and treatment. *Topics in companion animal medicine*, 27(3), 123-132.
2. Xenoulis, P. G. (2015). Diagnosis of pancreatitis in dogs and cats. *Journal of small animal practice*, 56(1), 13-26.

Vcheck cPL

Comparison of 3 types of PLI concentration measurement – Vcheck cPL test kit, IDEXX SNAP cPL test and IDEXX Reference Laboratories Spec cPL test

INTRODUCTION

Pancreatitis is the most common disorder of the exocrine pancreas in both dogs and cats. Antemortem diagnosis of canine and feline pancreatitis can be challenging. The clinical picture of dogs and cats with pancreatitis varies greatly (from very mild to severe or even fatal) and is characterized by non-specific findings. Serum pancreatic lipase immunoreactivity (PLI) concentration is currently considered to be the clinicopathological test of choice for the diagnosis of canine and feline pancreatitis. In clinical practice, a combination of careful evaluation of the animal's history, serum PLI concentration and abdominal ultrasonography, together with pancreatic cytology or histopathology when indicated or possible, is considered to be the most practical and reliable means for an accurate diagnosis or exclusion of pancreatitis compared with other diagnostic modalities.¹

Currently, there are various POC test kits commercially available. Vcheck cPL is an in vitro diagnostic test kit for the quantitative measurement of canine pancreatic lipase concentration in canine serum. IDEXX SNAP cPL Test is an in vitro test for the semi-quantitative measurement of pancreatic lipase levels in canine serum. The test result is displayed as a colored sample spot that must be compared to a reference spot. If the color intensity of the sample spot is lighter than the color intensity of the reference spot, cPL levels are normal. If the color intensity of the sample spot is equal to or darker than the color intensity of the reference spot, cPL levels are abnormal. If the SNAP cPL Test results are abnormal, it is recommended that veterinarians perform the Spec cPL Test as a followup to establish a baseline cPL concentration and to monitor treatment.² IDEXX Reference Laboratories provide the Spec cPL Test which measures the cPL concentration quantitatively.

STUDY DESIGN

At Eltham Veterinary Practice in Australia, 40 canine serum samples from the patients suspected of pancreatitis were run on the Vcheck cPL test (with a V200 analyzer) and the SNAP cPL assay to determine cPL concentration quantitatively and semi-quantitatively, respectively, in accordance with the manufacturer's instructions. The same samples were measured using the Spec cPL assay at IDEXX Reference Laboratories.

cPL concentration measured using Vcheck cPL and Spec cPL is interpreted as below.

cPL concentration	< 200ug/L	200 - 400ug/L	> 400ug/L
Interpretation	Normal	Elevated	Consistent with pancreatitis

RESULTS

Majority of the testing results were consistent with each other, Vcheck cPL, Spec cPL and SNAP cPL. But discrepancy was noted in 5 samples. 3 of them showed abnormal result in SNAP even though the cPL concentration was below 200 ug/L in both Vcheck cPL and Spec cPL. Refer to footnote 3) in [Table 2]. And the other 2 samples had conflicting results in Spec cPL test. Refer to footnote 1) in [Table 1] and footnote 4) in [Table 3].

SUMMARY AND CONCLUSION

The agreement rate between the Vcheck cPL test and the Spec cPL of IDEXX Reference Laboratories was 95%. And the Vcheck cPL test has a higher agreement rate (92.5%) to the SNAP cPL kit than the Spec cPL does (87.5%). The Vcheck cPL can provide the quantitative cPL concentration within only 5 minutes in-house so that veterinarians do not need to wait for a few days for the results from reference laboratories.

ACKNOWLEDGEMENTS

We would like to thank Dr. Gus Braniff and his colleagues at Eltham Veterinary Practice for conducting this comparison evaluation and providing the test results.

REFERENCE

1. P. G. Xenoulis. Diagnosis of pancreatitis in dogs and cats. *Journal of Small Animal Practice* (2015) 56, 13–26
2. IDEXX Laboratories Inc. SNAP cPL Test — reference laboratory accuracy pet-side

Table 1. Vcheck cPL and Spec cPL (n=40)

		Spec cPL		
		Normal < 200 ug/L	Equivocal 200 – 400 ug/L	Abnormal > 400 ug/L
Vcheck cPL	Normal < 200 ug/L	30	1 ¹⁾	0
	Equivocal 200 – 400 ug/L	0	4	0
	Abnormal > 400 ug/L	1 ²⁾	0	4

1) cPL concentration in the Spec cPL was slightly increased (202 ug/L) and the result of the SNAP cPL test was normal.

2) The result of the SNAP cPL was abnormal. The sample spot was much darker than the reference spot. And the patient died several days after the test.

Table 2. Vcheck cPL and SNAP cPL (n=40)

		SNAP cPL	
		Normal	Abnormal
Vcheck cPL	Normal < 200 ug/L	28	3 ³⁾
	Equivocal & abnormal ≥ 200 ug/L	0	9

3) The Spec cPL testing results were normal in all 3 samples.

Table 3. Spec cPL and SNAP cPL (n=40)

		SNAP cPL	
		Normal	Abnormal
Spec cPL	Normal < 200 ug/L	27	4 ⁴⁾
	Equivocal & abnormal ≥ 200 ug/L	1 ⁵⁾	8

4) 3 of 4 samples showed normal results in the Vcheck cPL test. In the other sample, the cPL concentration was significantly high (1338 ug/L) in the Vcheck cPL test.

5) cPL concentration in the Vcheck cPL was normal.

Vcheck fPL

Clinical Efficacy Assessment of Vcheck fPL

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

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.

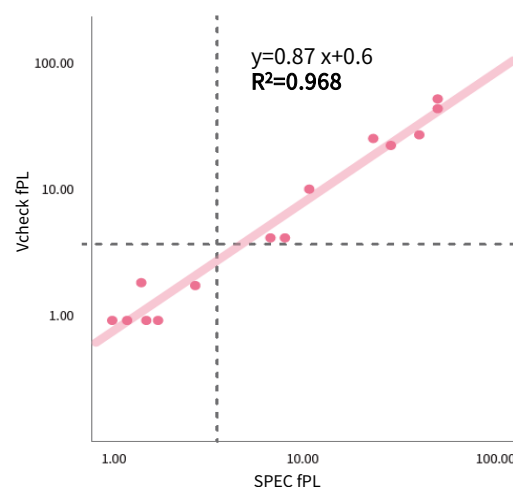


Figure 1. Comparison of BIONOTE Vcheck fPL and IDEXX SPEC fPL measurements in cats

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.

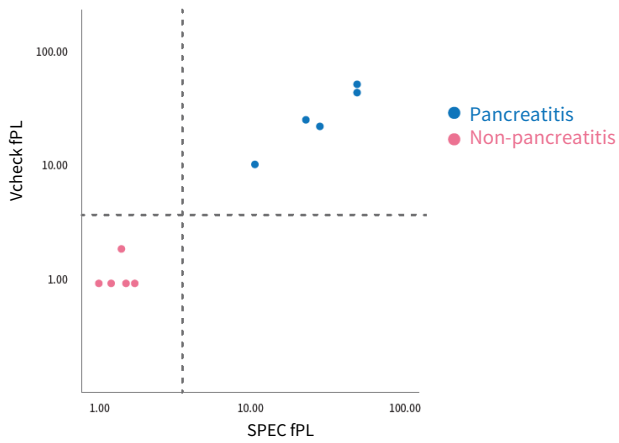


Figure 2. Comparison of definitive diagnosis of pancreatitis with BIONOTE Vcheck fPL and SPEC fPL in patients visiting the hospital for the first time

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.

Vcheck fPL

Evaluation of correlation between the BioNote Vcheck and a commercial ELISA for feline fPL

INTRODUCTION

Pancreatitis is important disease in cats. Chronic pancreatitis is recognized as the most common form of feline pancreatitis.¹ The diagnosis of chronic pancreatitis is much more challenging than in acute pancreatitis because changes tend to be less marked. The feline pancreas-specific lipase (fPL) is the most sensitive and specific serum marker for feline pancreatitis currently available.²

The BioNote Vcheck fPL is an in vitro fluorescent immunoassay test kit for the quantitative measurement of fPL concentration in feline serum. Since the kit provides quantitative measurement of fPL levels, BioNote Vcheck fPL can be tested to diagnose pancreatitis.

PURPOSE

This is to evaluate correlation between Vcheck and IDEXX SPEC fPL that provides the same diagnostic benefits as the original feline pancreas-specific lipase immunoreactivity (fPLI), in terms of measuring concentrations of feline serum fPL.

MATERIALS AND METHODS

The BioNote Vcheck fPL was carried out in accordance with the protocol provided by BioNote. The sensitivity and specificity of Vcheck fPL was evaluated using the test results from BioNote laboratory.

Fifty feline sera obtained from multiple animal hospitals in the Republic Korea were tested.

RESULTS

The test results for the 50 experimental feline sera were described in figure 1 and table 1. Samples had various fPL concentrations. 39 samples were above the normal range for fPL.

We used the IDEXX SPEC fPL ELISA results for these sera as a gold standard test. The diagnostic sensitivity for the BioNote Vcheck fPL was 94.8% and the diagnostic specificity was 100%.

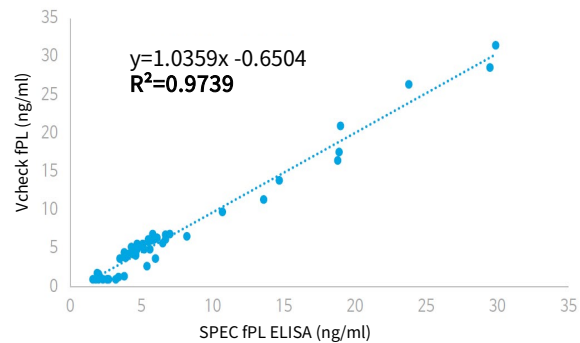


Figure 1. Correlation between Vcheck fPL and SPEC fPL ELISA (n=50)

Table 1. Correlation between normals and abnormal (n=50)

		Vcheck fPL	Spec fPL ELISA
< 3.5 ng/ml	Normal	13	11
3.5-5.4 ng/ml	Elevated	14	16
> 5.4 ng/ml	Consistent with pancreatitis	23	23

CONCLUSION

There were strong agreement between the two assays (IDEXX SPEC ELISA and the BioNote Vcheck) for fPL, which was 94%.

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2. Forman MA, Marks SL, De Cock HE, Hergeselle EJ, Wisner ER, Baker TW, Kass PH, Steiner JM, Williams DA. Evaluation of serum feline pancreatic lipase immunoreactivity and helical computed tomography versus conventional testing for the diagnosis of feline pancreatitis. Journal of veterinary internal medicine. 2004 Nov;18(6):807-15.

Vcheck cCortisol

Comparison of the Vcheck and IMMULITE 2000 methods for cortisol measurement in canine serum

Summary of *Medycyna Weterynaryjna* 77(08):6562-2021 (DOI:10.21521/mw.6562)

INTRODUCTION

Canine hyperadrenocorticism is an endocrine disease routinely encountered in primary care veterinary practices, with an estimated prevalence of 0.28%. Hypoadrenocorticism is an endocrinopathy in dogs, with prevalence ranging from 0.06% to 0.28%. In dogs, serum cortisol concentration can be useful for the diagnosis of adrenal and pituitary disorders. Interpretation of serum cortisol concentration is crucial in the diagnosis and management of dogs with both endocrine diseases.

PURPOSE

The aim of this study was to compare canine cortisol results obtained by the Vcheck analyzer with those obtained by the IMMULITE 2000 immunoassay, which had previously been validated for the measurement of serum cortisol concentration in dogs.

MATERIALS AND METHODS

Non-fasting blood samples were obtained from all 44 dogs. Cortisol concentration was measured with the IMMULITE 2000 (Siemens Healthcare Diagnostics, Deerfield, IL, USA) as a reference method, which uses a solid-phase competitive enzyme-amplified chemiluminescent immunoassay. They were concurrently determined using the Vcheck assay – an automated test for the quantitative determination of cortisol in canine serum – on the Vcheck analyzer. Cortisol values were compared using Pearson's Correlation analysis and simple regression analysis. Agreement between the two methods was calculated with a Bland-Altman plot.

RESULTS

Pearson's Correlation analysis shows a very high consistency with the results obtained by the two analyzers ($r=0.94$, Fig.1). The Bland-Altman test of agreement demonstrated that the Vcheck produced results close to those obtained by the reference method (Fig.2). The cortisol

concentrations obtained by the Vcheck and IMMULITE 2000 methods were highly comparable in this range of values, which includes the cortisol concentrations obtained after the ACTH administration.

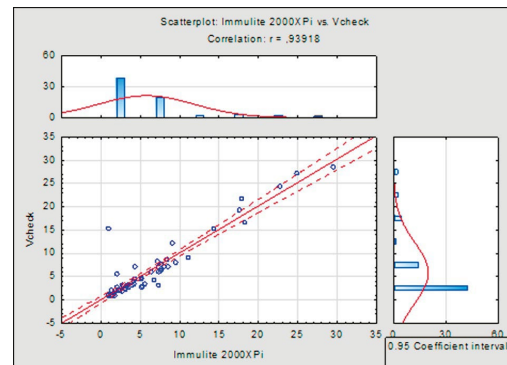


Fig. 1. Pearson's Correlation analysis ($r=0.94$)

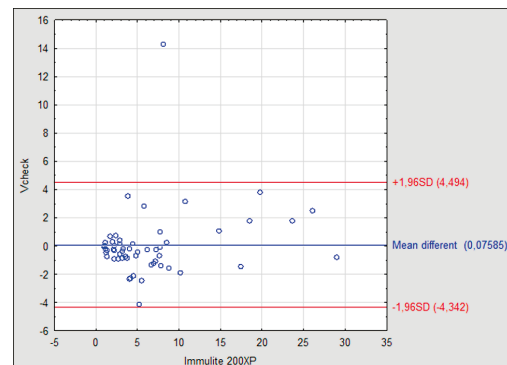


Fig. 2. Bland-Altman's plot (mean \pm 1.96 SD)

CONCLUSION

The Vcheck analyzer was fast and simple to operate. The rapidity of measurement (20 minutes), the small sample required (50 μ l), and the wide measurement range of the Vcheck method, together with its precision, linearity, and comparability to the reference method, make it suitable for canine serum cortisol analysis in samples obtained as part of dynamic endocrine function testing.

Vcheck T4

Evaluation of Correlation Between BIONOTE Vcheck T4 and IMMULITE T4

INTRODUCTION

T4 is a thyroid hormone that is likely the primary determinant of basal metabolism. Canine hypothyroidism is a commonly occurring endocrinopathy caused by decreased production of thyroid hormone. Feline hyperthyroidism is the most common endocrinopathy of older cats. It is important for clinician to screen patients with suspected thyroid disease because thyroid disease respond well to treatment.

Function of thyroid gland is typically assessed by measuring serum thyroid hormone concentration. Total T4 concentration is verified to diagnose thyroid disease and monitor medical treatment of these disease.

The BioNote Vcheck T4 is an in vitro immunoassay test kit for the quantitative measurement of canine or feline total T4 concentration in serum.

Since the kit provides quantitative measurement of total T4 levels, BioNote Vcheck T4 can be tested to diagnose canine hypothyroidism or feline hyperthyroidism.

PURPOSE

The objective of this test was to conduct comparison of T4 concentrations determined by the Vcheck T4 test with T4 concentrations determined by the IMMULITE® (Siemens Healthcare Diagnostics, Deerfield, IL, USA) used at veterinary reference laboratories.

MATERIALS AND METHODS

Total 92 (58 canine sera, 34 feline sera) sera samples were provided from animal hospital and university in Korea.

Tests were performed using Vcheck T4 and IMMULITE T4 according to the manufacturer's instruction.

RESULTS

The test results for the correlation between BioNote Vcheck T4 and IMMULITE T4 were described in figure 1 and figure 2. These samples had various T4 concentrations.

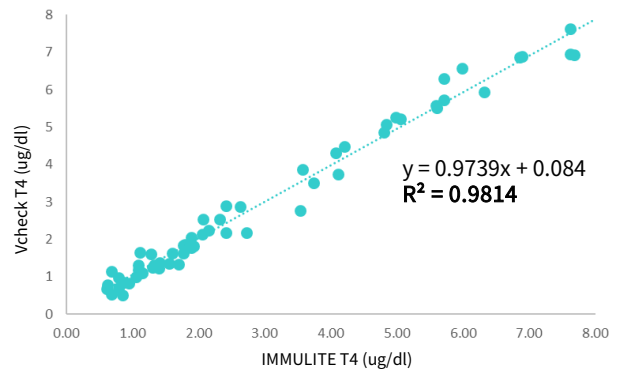


Figure 1. Correlation between the results of Vcheck T4 and IMMULITE T4 in canine samples (n=58)

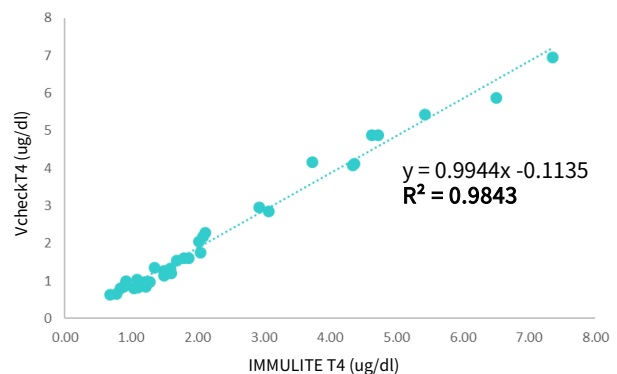


Figure 2. Correlation between the results of Vcheck T4 and IMMULITE T4 in feline samples (n=34)

CONCLUSION

Through this study, it was revealed that the Vcheck T4 shows good concordance rate with IMMULITE T4 (canine R^2 0.9814; feline R^2 0.9843).

Based on these results, the Vcheck T4 provides accurate and reliable T4 analysis in serum samples from dogs and cats, as compared to a reference method.

RAW DATA

Canine serum sample (n=58)

No.	Immulite (ug/dl)	Vcheck (ug/dl)	No.	Immulite (ug/dl)	Vcheck (ug/dl)
1	0.611	0.68	30	2.07	2.53
2	0.63	0.79	31	2.15	2.25
3	0.68	0.54	32	2.32	2.54
4	0.681	1.15	33	2.41	2.89
5	0.786	0.97	34	2.41	2.17
6	0.79	0.71	35	2.63	2.88
7	0.853	0.52	36	2.73	2.17
8	0.88	0.84	37	3.54	2.77
9	0.947	0.83	38	3.57	3.86
10	1.05	0.99	39	3.74	3.51
11	1.09	1.31	40	4.07	4.32
12	1.09	1.18	41	4.11	3.75
13	1.11	1.66	42	4.21	4.49
14	1.15	1.11	43	4.8	4.87
15	1.28	1.61	44	4.84	5.07
16	1.31	1.26	45	4.98	5.27
17	1.33	1.31	46	5.06	5.22
18	1.4	1.23	47	5.59	5.57
19	1.41	1.38	48	5.6	5.51
20	1.56	1.35	49	5.71	6.29
21	1.6	1.62	50	5.71	5.72
22	1.7	1.34	51	5.98	6.57
23	1.77	1.62	52	6.32	5.94
24	1.77	1.84	53	6.86	6.86
25	1.79	1.86	54	6.89	6.88
26	1.89	1.77	55	7.62	7.62
27	1.89	2.05	56	7.62	6.95
28	1.93	1.81	57	7.68	6.93
29	2.06	2.14	58	8.01	7.67

Feline serum sample (n=34)

No.	Immulite (ug/dl)	Vcheck (ug/dl)	No.	Immulite (ug/dl)	Vcheck (ug/dl)
1	0.679	0.65	18	1.68	1.55
2	0.775	0.66	19	1.79	1.61
3	0.837	0.81	20	1.86	1.61
4	0.878	0.85	21	2.01	2.05
5	0.919	1	22	2.04	1.77
6	1.03	0.82	23	2.07	2.18
7	1.08	1.05	24	2.11	2.3
8	1.09	0.83	25	2.93	2.96
9	1.2	0.98	26	3.07	2.86
10	1.22	0.86	27	3.72	4.16
11	1.27	0.98	28	4.34	4.09
12	1.35	1.35	29	4.36	4.12
13	1.49	1.27	30	4.62	4.89
14	1.49	1.14	31	4.72	4.88
15	1.59	1.34	32	5.42	5.44
16	1.59	1.25	33	6.5	5.89
17	1.6	1.22	34	7.35	6.95

Vcheck cTSH

Evaluation of Correlation Between BIONOTE Vcheck cTSH and IMMULITE canine TSH

INTRODUCTION

Thyroid-stimulating hormone (TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroid hormones.

Canine hypothyroidism is a commonly occurring endocrinopathy caused by decreased production of thyroid hormone. Function of thyroid gland is typically assessed by measuring serum thyroid hormone (T4) and TSH concentration. Results of TSH assay is interpreted in conjunction with result of T4 assay. A serum TSH concentration greater than reference range is consistent with hypothyroidism. It is also used to differentiate primary hypothyroidism, secondary hypothyroidism, and euthyroid sick syndrome.

The BioNote Vcheck cTSH is an in vitro immunoassay test kit for the quantitative measurement of canine TSH concentration in serum. Since the kit provides quantitative measurement of TSH concentration, BioNote Vcheck cTSH can be tested to diagnose canine hypothyroidism.

PURPOSE

The objective of this test was to conduct comparison of TSH concentrations determined by the Vcheck cTSH test with TSH concentrations determined by the IMMULITE® (Siemens Healthcare Diagnostics, Deerfield, IL, USA) used by reference laboratories.

MATERIALS AND METHODS

Total 52 sera samples were provided from animal hospital and university in Korea.

Tests were performed using Vcheck cTSH and IMMULITE canine TSH according to the manufacturer's instruction.

RESULTS

The test results for the correlation between BioNote Vcheck cTSH and IMMULITE canine TSH were described in figure 1. These samples had various TSH concentrations.

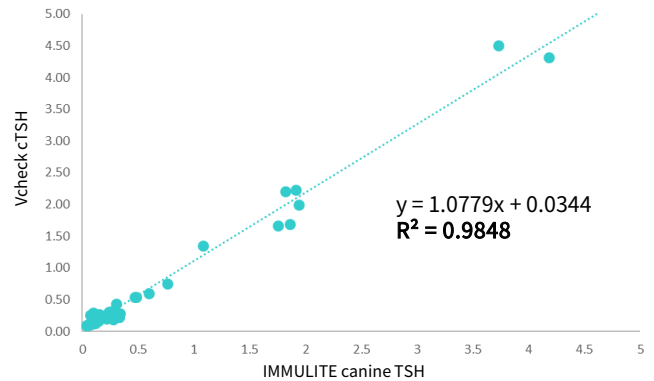


Figure 1. Correlation between Vcheck cTSH and IMMULITE canine TSH (n=52)

CONCLUSION

Through this study, it was revealed that the Vcheck cTSH shows good concordance rate with IMMULITE ($R^2=0.9848$).

The test results indicate that Vcheck cTSH has good correlation with IMMULITE that used in reference laboratories. Therefore Vcheck cTSH provides accurate results for diagnosis of canine hypothyroidism in-house.

RAW DATA

Canine serum sample (n=52)

No.	Immolute (ng/ml)	Vcheck (ng/ml)	No.	Immolute (ng/ml)	Vcheck (ng/ml)
1	0.039	0.1	27	0.159	0.23
2	0.04	0.09	28	0.165	0.2
3	0.052	0.09	29	0.19	0.22
4	0.066	0.11	30	0.215	0.2
5	0.068	0.13	31	0.229	0.28
6	0.07	0.26	32	0.236	0.3
7	0.076	0.15	33	0.245	0.31
8	0.078	0.13	34	0.264	0.28
9	0.082	0.14	35	0.266	0.32
10	0.088	0.17	36	0.27	0.29
11	0.09	0.16	37	0.278	0.19
12	0.091	0.12	38	0.303	0.43
13	0.094	0.29	39	0.333	0.22
14	0.095	0.14	40	0.337	0.28
15	0.099	0.16	41	0.472	0.54
16	0.104	0.17	42	0.486	0.54
17	0.107	0.17	43	0.593	0.6
18	0.11	0.22	44	0.765	0.75
19	0.117	0.19	45	1.08	1.35
20	0.117	0.13	46	1.75	1.67
21	0.123	0.16	47	1.82	2.21
22	0.134	0.17	48	1.86	1.69
23	0.136	0.2	49	1.91	2.23
24	0.142	0.21	50	1.94	2
25	0.146	0.17	51	3.73	4.5
26	0.148	0.27	52	4.18	4.32

Vcheck cProgesterone

Evaluation of Correlation Between BIONOTE Vcheck Canine Progesterone and IMMULITE

INTRODUCTION

Progesterone (P4) is a steroid hormone and part of the group of sex hormones. It involved in the estrus cycle and pregnancy. Progesterone concentration is increased during estrus. Progesterone concentration drop to basal levels for parturition to occur. Progesterone concentration remains at basal levels through anestrus, until ovulation during the next estrous cycle.

The LH surge and subsequent ovulation occur spontaneously in bitches. Progesterone concentrations begin to increase above basal levels as a preovulatory event. This initial rise occurs simultaneously with the LH surge. Therefore, progesterone can be used to approximate the LH surge and predict impending ovulation in bitches.

The Vcheck Canine Progesterone Test Kit (Vcheck cProgesterone) is based on competitive immunoassay method for the quantitative measurement of canine progesterone concentration.

Since the kit provides quantitative measurement of progesterone levels, BioNote Vcheck cProgesterone can be used to determine the ovulation timing to determine breeding dates. It can be also used to predict the whelping date.

PURPOSE

The objective of this test was to conduct comparison of progesterone concentrations determined by the Vcheck cProgesterone test with progesterone concentrations determined by the IMMULITE® (Siemens Healthcare Diagnostics, Deerfield, IL, USA) used in reference laboratories.

MATERIALS AND METHODS

Total 64 sera samples were provided from animal hospital and university in Korea. All samples were analyzed with Vcheck cProgesterone and a IMMULITE progesterone according to the manufacturer's instruction.

RESULTS

The test results for the correlation between BioNote Vcheck cProgesterone and IMMULITE

progesterone is shown in figure 1. The Vcheck cProgesterone demonstrates excellent correlation with IMMULITE that used in reference laboratories. These samples had various progesterone concentrations.

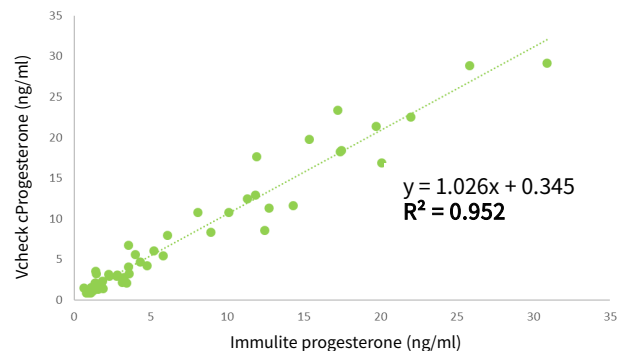


Figure 1. Correlation between Vcheck cProgesterone and IMMULITE progesterone

CONCLUSION

Through this study, it was revealed that the Vcheck cProgesterone shows excellent concordance rate with IMMULITE progesterone ($R^2=0.952$). The Vcheck cProgesterone can provide an accurate and reliable results in-house.

RAW DATA

Canine serum sample (n=64)

No.	Immolute (ng/ml)	Vcheck (ng/ml)	No.	Immolute (ng/ml)	Vcheck (ng/ml)
1	0.6	1.47	33	2.77	2.99
2	0.8	0.9	34	2.80	3.09
3	0.809	0.9	35	3.13	2.21
4	0.89	0.9	36	3.27	2.77
5	0.91	0.9	37	3.41	2.13
6	0.93	1.11	38	3.52	4.06
7	1	0.9	39	3.53	6.73
8	1.02	1.03	40	3.59	3.27
9	1.05	0.9	41	3.99	5.60
10	1.08	1.41	42	4.28	4.72
11	1.08	1.30	43	4.73	4.29
12	1.11	1.57	44	5.17	6.05
13	1.13	1.07	45	5.81	5.45
14	1.27	1.51	46	6.06	7.97
15	1.29	1.30	47	8.07	10.82
16	1.32	1.46	48	8.90	8.37
17	1.33	1.62	49	10.09	10.84
18	1.36	1.49	50	11.3	12.47
19	1.36	2.14	51	11.8	12.91
20	1.38	3.53	52	11.9	17.67
21	1.43	1.81	53	12.41	8.62
22	1.43	3.25	54	12.7	11.33
23	1.45	1.91	55	14.3	11.62
24	1.47	2.04	56	15.33	19.83
25	1.55	1.79	57	17.20	23.38
26	1.57	1.37	58	17.35	18.24
27	1.76	1.70	59	17.43	18.46
28	1.76	1.77	60	19.70	21.38
29	1.85	2.32	61	20.05	16.93
30	1.89	1.43	62	21.95	22.52
31	2.24	3.15	63	25.8	28.86
32	2.26	2.99	64	30.88	29.22

Vcheck Canine Antibody Titer

Serological testing for antibodies against canine parvovirus in a population of adult dogs in eastern Poland

Summary of *Medycyna Weterynaryjna* 77(05):6523-2021 (DOI: 10.21521/mw.6523)

INTRODUCTION

Canine parvovirus is a systemic disease caused by CPV-2 (canine parvovirus type 2). The typical symptoms of parvovirus include lack of appetite, vomiting and bloody diarrhea. The most effective way of preventing parvovirus is prophylactic vaccination.

The aim of the study was to determine the titre of antibodies against CPV in groups of adult dogs from eastern Poland with varied history of vaccination against parvovirus.

MATERIALS AND METHODS

Based on the history of vaccination against CPV, the animals were divided into three groups.

- Group I (n = 59): animals regularly vaccinated against the disease according to WSAVA guidelines
- Group II (n = 77): animals that completed the full course of CPV immunization as puppies but had not received a booster dose in the past three years
- Group III (n = 64): animals that had not received even a single vaccination against parvovirus

Blood was collected from all dogs to determine the titres of antibodies against CPV using a Bionote V200 analyzer. The protective titre of antibodies against CPV in the hemagglutination inhibition test was considered to be $\geq 1:80$.

RESULTS

In group I, antibody titres equal to or higher than HI = 80, thought of as ensuring resistance to infection were observed in 86% of dogs, while 14% of the tested animals had HI < 80. In groups II and III, high anti-CPV antibody titres of HI ≥ 80 were found in 73% and 72% dogs, respectively. Statistical analysis showed a significantly greater number of dogs with high titres of antibodies against CPV of HI ≥ 80 in group I compared to the other two groups ($p = 0.0006$, $p = 0.0001$, respectively).

Also, gender and race were not found to influence the value of titres of antibodies against CPV.

Table 1. Values of antibody titre in HI test for CPV in dogs from particular groups in the study; number (%)

Titer HI	Number (%) of dogs in		
	Group I n = 59	Group II n = 77	Group III n = 64
HI < 80	8 (14)	21 (27)	18 (28)
HI ≥ 80	51 (86)	56 (73)	46 (72)

Table 2. Values of antibody titre for CPV in the group of purebreed, mixed-breed, male and female dogs used in the study; number (%)

Titer HI	Number (%) of dogs in			
	Mixed-breed	Pure-breed	Males	Females
HI < 80	28 (25)	19 (22)	22 (23)	25 (24)
HI ≥ 80	86 (75)	67 (78)	73 (77)	80 (76)

CONCLUSION

Regular vaccinations in accordance with WSAVA recommendations increase protection against CPV, as evidenced by the lowest percentage of dogs with HI < 80 in group I dogs vaccinated at least every 3 years. Also, the presence of dogs with high titres of antibodies against CPV in group III indicates widespread contamination of the environment with this pathogen.

The use of serological tests for parvovirus seems to be of crucial importance for medical and veterinary practice, indicating the possible need to modify its vaccination plan, as well as the need for special treatment and isolation of animals unable to develop resistance to this virus.

Vcheck Canine Antibody Titer

Evaluation of Vcheck Canine Antibody Tests for the Detection of Protective Antibodies

INTRODUCTION

The canine viruses which cause distemper, parvoviral enteritis, and infectious hepatitis have a high correlation between the presence of antibody and protective immunity. Core vaccines are recommended for all puppies and dogs with an unknown vaccination history. These core vaccines include: canine distemper virus (CDV), canine adenovirus (CAV) and canine parvovirus type 2 (CPV-2). It is recommended to use an in-house serological testing for antibodies specific for vaccine antigens following vaccination.

The Vcheck CPV, CDV or CAV Ab Test is a one-step rapid test for the semi-quantitative detection of antibodies to parvovirus, distemper virus or adenovirus in canine serum or plasma. The purpose of this study is to verify the performance of the Vcheck compared to the gold standard test for CPV, CDV and CAV antibody titers.

MATERIALS AND METHODS

CPV Ab titer test:

A total of 56 random canine serum samples were tested by Vcheck CPV Ab test kit according to manufacturer's instructions (BioNote, Korea). The Vcheck result of medium (3, 3.5) or high titer (from 4 to 6) is considered having a 'high' protective antibody, while one of negative (0) or low titer (1, 2) is considered having a 'low' protective antibody. They were also referred to Cornell University College of Veterinary Medicine (CUCVM) for Hemagglutination Inhibition (HI) test and evaluated with a commercial in-practice test (product 'I'). A titer result of 1:80 or greater is considered as 'high'.

CDV Ab (CAV Ab) titer test:

A total of 129 (219) random canine serum samples were tested by Vcheck CDV Ab (CAV Ab) test kit according to manufacturer's instructions. The Vcheck result of medium (3, 3.5) or high titer (from 4 to 6) is considered having a 'high' protective antibody, while one of negative (0) or low titer (1, 2) is considered having a 'low' protective antibody. They were also referred to CUCVM for Virus Neutralization (VN) test and evaluated with a commercial in-practice test (product 'I'). A titer result of 1:32 (1:16) or greater is considered as 'high'.

RESULTS

The Vcheck antibody tests demonstrated higher sensitivities and specificities than commercially available 'I' kit, compared against the reference tests; The CPV Ab Test showed 100% sensitivity and 85.7% specificity, CDV Ab Test 100 and 83.1%, CAV Ab Test 87.8 and 98.2%. On the contrary, 'I' kit had 95.9% sensitivity and 71.4% specificity in CPV Ab, 97.1 and 79.7% in CDV Ab, 84.8 and 92.7% in CAV Ab (Refer to Table 1, 2 and 3).

CONCLUSION

The findings of the present study indicated that the Vcheck showed higher correlation with the gold standard tests (HI, VN test) than or equal to a commercial product 'I', so it can be used as a useful method of serological testing due to its rapidity and ease of performance, providing accurate antibody titer results against CPV, CDV and CAV in-house.

REFERENCE

1. WSAVA GUIDELINES FOR VACCINATION OF DOGS AND CATS, Journal of Small Animal Practice – Vol 57, January 2016

Table 1. Correlation of Vcheck CPV Ab test and a commercial 'I' kit with HI test

Comparative Evaluation		Commercial 'I' kit		Total	Vcheck CPV Ab		Total
		High	Low		High	Low	
HI Test (Cornell Univ.)	High	47	2	49	49	0	49
	Low	2	5	7	1	6	7
Total		49	7	56	50	6	56
Sensitivity		95.9% (47/49)			100% (49/49)		
Specificity		71.4% (5/7)			85.7% (6/7)		
Overall Agreement		92.9% (52/56)			98.2% (55/56)		

Table 2. Correlation of Vcheck CDV Ab test and a commercial 'I' kit with VN test

Comparative Evaluation		Commercial 'I' kit		Total	Vcheck CDV Ab		Total
		High	Low		High	Low	
VN Test (Cornell Univ.)	High	68	2	70	70	0	70
	Low	12	47	59	10	49	59
Total		80	49	129	80	49	129
Sensitivity		97.1% (68/70)			100% (70/70)		
Specificity		79.7% (47/59)			83.1% (49/59)		
Overall Agreement		89.1% (115/129)			92.2% (119/129)		

Table 3. Correlation of Vcheck CAV Ab test and a commercial 'I' kit with VN test

Comparative Evaluation		Commercial 'I' kit		Total	Vcheck CAV Ab		Total
		High	Low		High	Low	
VN Test (Cornell Univ.)	High	139	25	164	144	20	164
	Low	4	51	55	1	54	55
Total		143	76	219	145	74	219
Sensitivity		84.8% (139/164)			87.8% (144/164)		
Specificity		92.7% (51/55)			98.2% (54/55)		
Overall Agreement		86.8% (190/219)			90.4% (198/219)		

Vcheck Feline Antibody Titer

Evaluation of Vcheck Feline Antibody Tests for the Detection of Protective Antibodies

INTRODUCTION

Feline distemper, caused by feline panleukopenia virus (FPV), is a severe, highly contagious viral disease of cats. Feline calicivirus (FCV) and feline herpesvirus type 1 (FHV-1) are the two primary causes of upper respiratory disease in cats.¹ The core vaccines for the cat are those that protect against FPV, FHV-1, and FCV. The presence of antibodies in adult cats acquired through previous vaccination or exposure to field virus correlates with the protection against infection.² The FHV, FCV vaccines will not completely prevent an infection from occurring if a cat is exposed to the virus, but it will greatly reduce the severity of the infection.

The Vcheck FPV, FHV or FCV Ab Test is a one-step rapid test for the semi-quantitative detection of antibodies to panleukopenia virus, herpesvirus or calicivirus in feline serum or plasma. The purpose of this study is to verify the performance of the Vcheck compared to the gold standard test for FPV, FHV, and FCV antibody titers.

MATERIALS AND METHODS

FPV Ab titer test:

A Total of 45 random feline serum samples were tested by Vcheck FPV Ab test kit according in accordance to the manufacturer's instructions (BioNote, Korea). The Vcheck result of medium (3, 3.5) or high titer (from 4 to 6) is considered having a 'high' protective antibody, while one of negative (0) or low titer (1, 2) is considered having a 'low' protective antibody. They were also referred to Cornell University College of Veterinary Medicine (CUCVM) for Hemagglutination Inhibition (HI) test and evaluated with a commercial in-practice test ('I' kit). A titer result of 1:80 or greater is considered as 'high'.

FHV Ab (FCV Ab) titer test:

A Total of 86 (75) random feline serum samples were tested by Vcheck FHV Ab (FCV Ab) test kit in accordance to the manufacturer's instructions. The Vcheck result of medium (3, 3.5) or high titer (from 4 to 6) is considered having a 'high' protective antibody, while one of negative (0) or low titer (1, 2) is considered having a 'low' protective antibody. They were also referred to

CUCVM for Virus Neutralization (VN) test and evaluated with a commercial in-practice test ('I' kit). A titer result of 1:16 (1:32) or greater is considered as 'high'.

RESULTS

The Vcheck antibody tests demonstrated higher sensitivities and specificities than or equal to a commercially available 'I' kit, compared against the reference tests; The FPV Ab Test showed 100% sensitivity and 95.2% specificity, FHV Ab Test 100 and 91.5%, FCV Ab Test 92.7 and 85.3%. On the contrary, 'I' kit had 100% sensitivity and 95.2% specificity in FPV Ab, 100 and 71.2% in FHV Ab, 92.7 and 79.4% in FCV Ab (Refer to Table 1, 2 and 3).

CONCLUSION

The findings of the present study indicated that the Vcheck showed higher correlation with the gold standard tests (HI, VN test) than or equal to a commercial product 'I', so it can be used as a useful method of serological testing due to its rapidity and ease of performance, providing accurate antibody titer results against FPV, FHV and FCV in-house.

REFERENCE

1. WSAVA GUIDELINES FOR VACCINATION OF DOGS AND CATS, Journal of Small Animal Practice – Vol 57, January 2016
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Table 1. Correlation of Vcheck FPV Ab test and a commercial 'I' kit with HI test

Comparative Evaluation		Commercial 'I' kit		Total	Vcheck FPV Ab		Total
		High	Low		High	Low	
HI Test (Cornell Univ.)	High	24	0	24	24	0	24
	Low	1	20	21	1	20	21
Total		25	20	45	25	20	45
Sensitivity		100 % (24/24)			100 % (24/24)		
Specificity		95.2 % (20/21)			95.2 % (20/21)		
Overall Agreement		97.8 % (44/45)			97.8 % (44/45)		

Table 2. Correlation of Vcheck FHV Ab test and a commercial 'I' kit with VN test

Comparative Evaluation		Commercial 'I' kit		Total	Vcheck FHV Ab		Total
		High	Low		High	Low	
VN Test (Cornell Univ.)	High	27	0	27	27	0	27
	Low	17	42	59	5	54	59
Total		44	42	86	32	54	86
Sensitivity		100 % (27/27)			100% (27/27)		
Specificity		71.2 % (42/59)			91.5 % (54/59)		
Overall Agreement		80.2 % (69/86)			94.2 % (81/86)		

Table 3. Correlation of Vcheck FCV Ab test and a commercial 'I' kit with VN test

Comparative Evaluation		Commercial 'I' kit		Total	Vcheck FCV Ab		Total
		High	Low		High	Low	
VN Test (Cornell Univ.)	High	38	3	41	38	3	41
	Low	7	27	34	5	29	34
Total		45	30	75	43	32	75
Sensitivity		92.7 % (38/41)			92.7 % (38/41)		
Specificity		79.4 % (27/34)			85.3 % (29/34)		
Overall Agreement		86.7 % (65/75)			89.3 % (67/75)		



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