Training will be started at 10:10 AM(GMT +2)

Please chat us or speak if you would need any assistance

All participants would be muted to eliminate noise while presentation

BIONOTE

Vcheck cPL/fPL

Eiden Choi
Overseas Sales Team

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CONTENTS

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01 Vcheck cPL/fPL

- Pancreatitis

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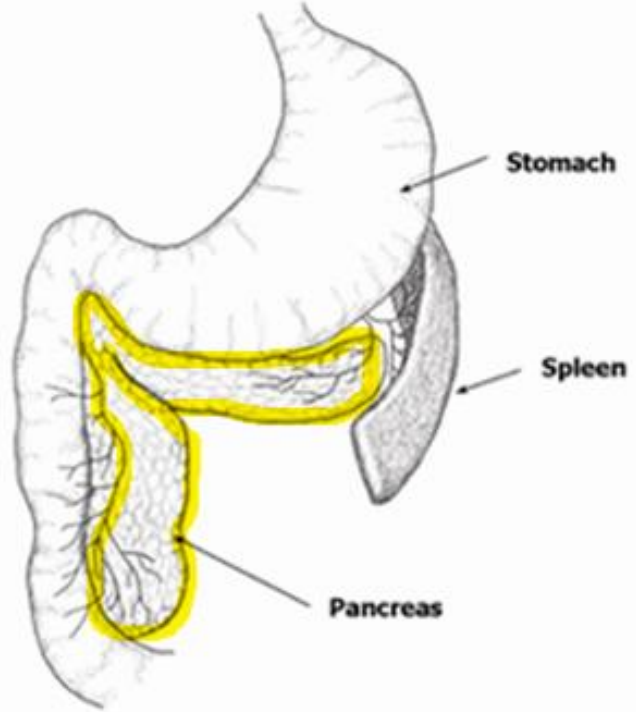
01 Vcheck cPL/fPL – Pancreatitis

- What is Pancreatitis?



✓ Pancreas: an organ of the digestive and endocrine system
- Endocrine portion: produce insulin and control metabolism/blood glucose
- Exocrine portion: produce digestive enzymes for digestion

✓ Pancreatitis: Inflammation of the pancreas
- Acute Pancreatitis
- Chronic Pancreatitis

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01 Vcheck cPL/fPL – Pancreatitis

Acute vs. Chronic Pancreatitis

- Based on histologic features – not necessarily clinical

	Acute	Chronic	Chronic active
Histology	Inflammation with neutrophils Pancreatic necrosis, edema, peripancreatic fat necrosis	Infiltration of mononuclear cells, fibrosis, nodular hyperplasia	As chronic but with neutrophilic inflammation
Reversibility	often reversible May lead to chronic	Irreversible	Irreversible
Clinical features	Mild to severe & fatal (necrotizing(cell death))	Generally mild	May be severe

BSAVA Canine and Feline Clinical Pathology

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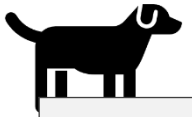
01 Vcheck cPL/fPL – Pancreatitis

- Clinical signs



Pancreatitis in dog

Dog: Pancreatitis	
Clinical signs	• Anorexia (91%) • Vomiting (90%) • Weakness (79%) • Abdominal pain (58%) • Dehydration (46%) • Diarrhea (33%)
✓ Mild cases : subclinical ✓ Severe cases : Systemic clinical signs such as fever or even cardiovascular shock	

Pancreatitis in cat

Cat: Pancreatitis	
Clinical signs	• Lethargy (100%) • Anorexia (97%) • Dehydration (92%) • Hypothermia (68%) • Vomiting (35%) • Abdominal pain (25%) • A palpable abdominal mass (23%) • Dyspnea (20%) • Ataxia (15%) • Diarrhea (15%)
✓ Less specific clinical signs ✓ Low incidence of vomiting and abdominal pain	

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01 Vcheck cPL/fPL – Diagnosis of Pancreatitis

Diagnosis of Pancreatitis

- A combination of history, clinical signs, PLI, ultrasonography ± cytology / histopathology

Method	Monitoring/Detect	Characteristic
Chemistry	Amylase/Lipase activity	Not specific. Lipase and amylase are secreted by pancreas and other organs(liver, intestine..)
Radiographic	Pancreas	Non-specific changes, Low sensitivity To identify foreign bodies in vomiting dogs
Ultrasonography	Pancreas	Specific, sensitive Operator-dependent, expensive
TLI(Trypsin-like Immunoreactivity)	EPI(Exocrine Pancreatic Insufficiency)	Low sensitivity Short half-life
cPL/fPL	Pancreas-specific Lipase	High sensitivity Easy and Fast diagnosis

NOTE

01 Vcheck cPL/fPL – Diagnosis of Pancreatitis

Pancreatic Lipase Immunoreactivity (PLI)

- Detection of pancreatic lipase by use of specific antibody
- Measuring pancreatic lipase exclusively

- Diagnostic and monitoring test
- Screening test (rule-out)

  ※ Long-term oral administration of prednisone did not have any affect on serum cPLI

- Most sensitive and specific diagnostic tool currently available
  - Sensitivity > 80% for dogs with acute clinical pancreatitis
  - Sensitivity > 60% for dogs with mild pancreatitis

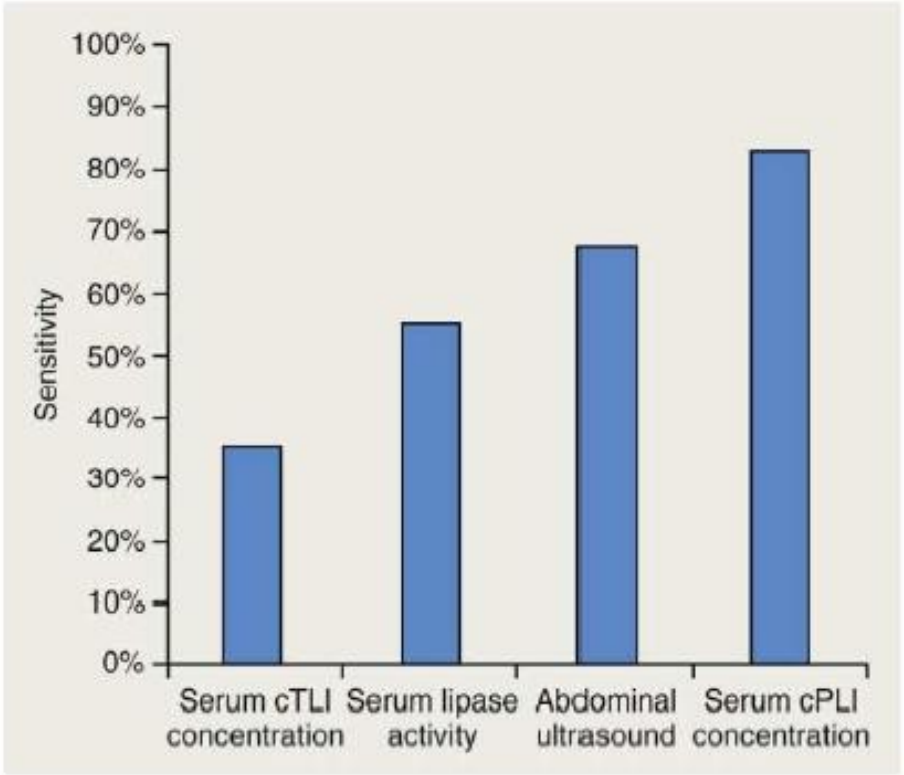

Figure 282-3 Comparison of the sensitivity for different diagnostic modalities for the diagnosis of canine pancreatitis. Note that serum trypsin-like immunoreactivity *(cTLI)* concentration, abdominal ultrasound, and serum pancreatic lipase immunoreactivity *(cPLI)* concentration have a high specificity for canine pancreatitis, whereas only approximately 50% of dogs with an elevated serum lipase activity have pancreatitis.[39,43]

Reference: Ettinger 7th edition

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01 Vcheck cPL/fPL – Diagnosis of Pancreatitis

CRP + cPL Test recommended to predict prognosis

Table 3. Time-course (days 1 to 5) change of C-reactive protein (CRP) concentration in survivors and nonsurvivors

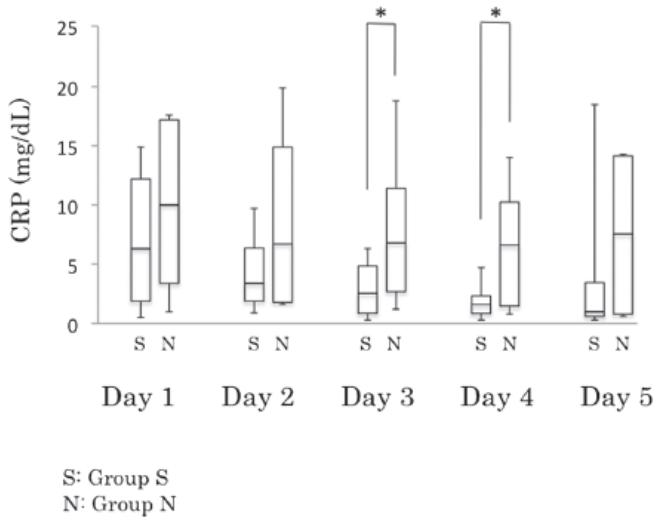
Days	Median value (range), mg/dl		*P*-value
	Survivors	Nonsurvivors	
Day 1	6.3 (0.5–14.9)	10 (1.0–17.6)	0.3592
Day 2	3.4 (0.9–9.7)	6.7 (1.6–19.9)	0.3081
Day 3	2.55 (0.3–6.3)	6.8 (1.2–18.8)	0.0252[a)]
Day 4	1.6 (0.3–4.7)	6.6 (0.8–14)	0.0438[a)]
Day 5	1.0 (0.3–18.5)	7.55 (0.6–14.3)	0.3948

a) $P<0.05$.

Table 4. Differences in the number of survivors and nonsurvivors on days 3 and 4, categorized by C-reactive protein (CRP) concentration (cutoff 6.5 mg/dl)

Days	Groups	No.	No.	*P*-value
		CRP ≥ 6.5 mg/dl	CRP < 6.5 mg/dl	
Day 3	Survivors	0	15	0.0048[a)]
	Nonsurvivors	4	3	
Day 4	Survivors	0	15	0.0048[a)]
	Nonsurvivors	4	3	

a) $P<0.05$.



S: Group S
N: Group N

Group S: Survived pancreatitis patient
Group N: Non-survived pancreatitis patient

* Assesment of severity and changes in C-reactive protein concentration and various biomarkers in dogs with pancreatitis, Japan

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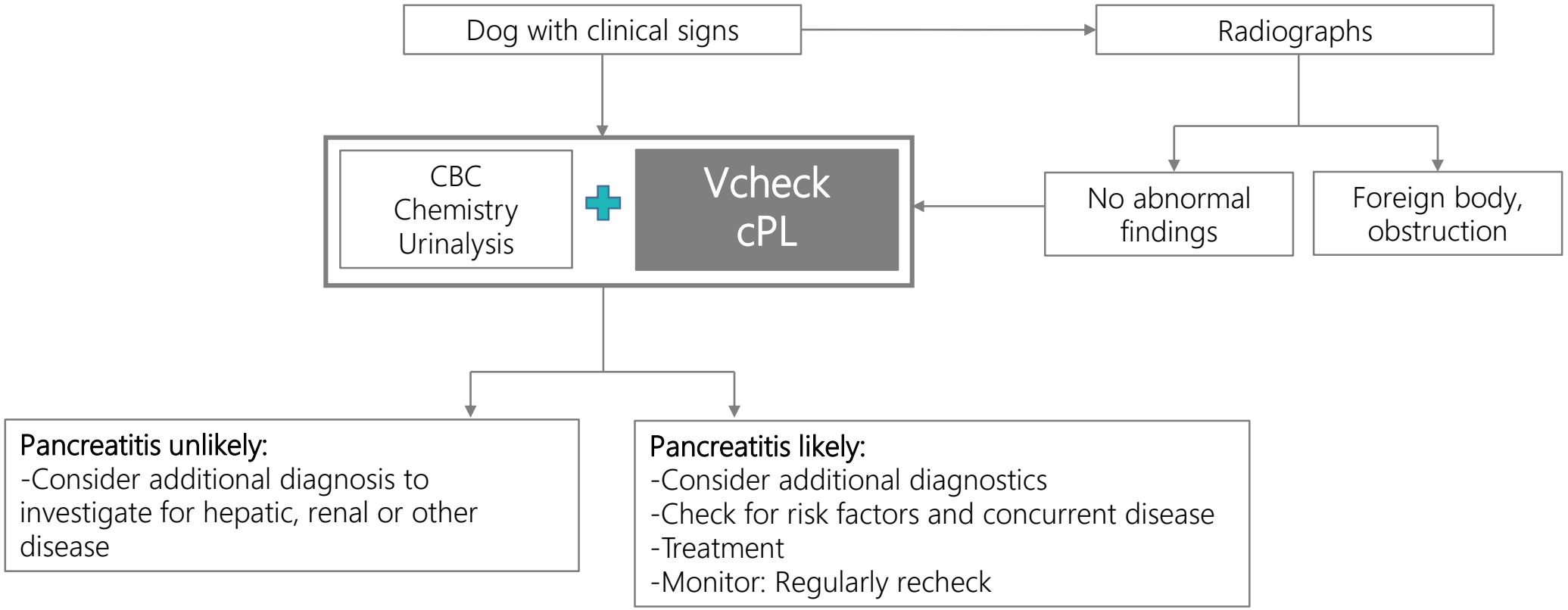
01 Vcheck cPL/fPL – Diagnosis of Pancreatitis

- cPL diagnosis algorithm



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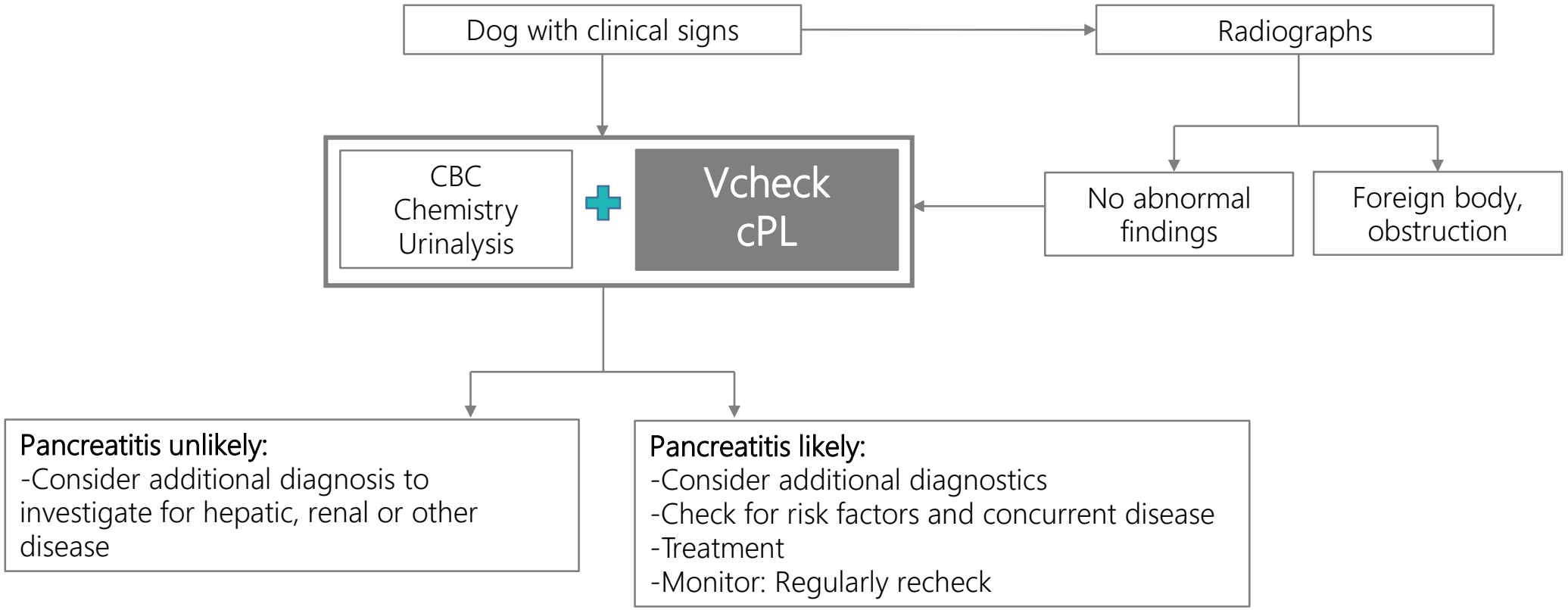
01 Vcheck cPL/fPL – Diagnosis of Pancreatitis

- cPL diagnosis algorithm



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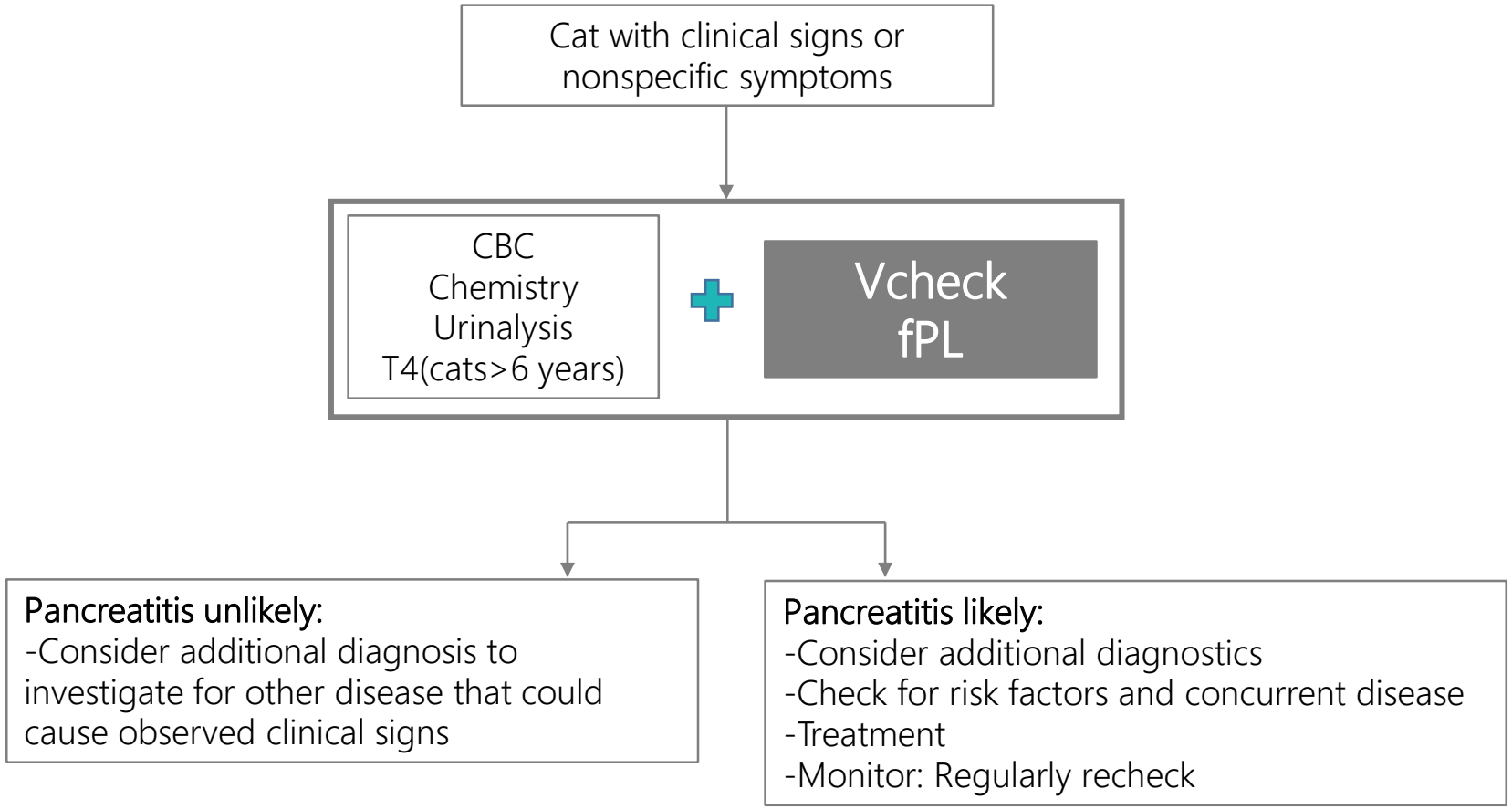
01 Vcheck cPL/fPL – Diagnosis of Pancreatitis

- fPL diagnosis algorithm



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02 Vcheck cPL & fPL

- Case Study – cPL/fPL

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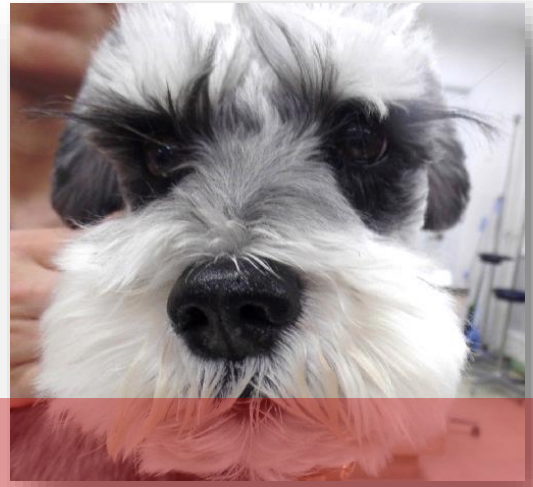
Case Study – cPL/fPL

Case #1 (misdiagnosis)

- 9 yrs, CM, M. Schnauzer
- CC : Pancreatitis (LAH)
- HPI(History of present Illness)
  - Chronic vomiting, mucous feces, abd. Pain
  - Hospitalized at LAH with monitoring of lipase level
  - Currently normal feces without abd. pain
- CRP & CPL Testing
  - **cPL** : 37 ng/mL (*Reference: normal <200 ng/ml)
  - **CRP** : <10 mg/L (*Reference: normal <20 mg/L)

	Ref	Day 1	Day 5	Day 10	Day 14
Lipase	135-755	810	1018	1278	985



No pancreatitis!

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Case Study – cPL/fPL

Case #2 (misdiagnosis)

- 5 yrs, CM, Maltese
- CC : chronic pancreatitis, CRP elevated
- HPI
  - **4 months ago**: lethargy
  - **3 months ago**: vomiting and mild fever (39.4°C)
  - **2 months ago**: CRP elevated, abnormal SNAP cPL kit, normal Vcheck cPL (142 ug/L)
  - **1 month ago**: pancreatitis diagnosed

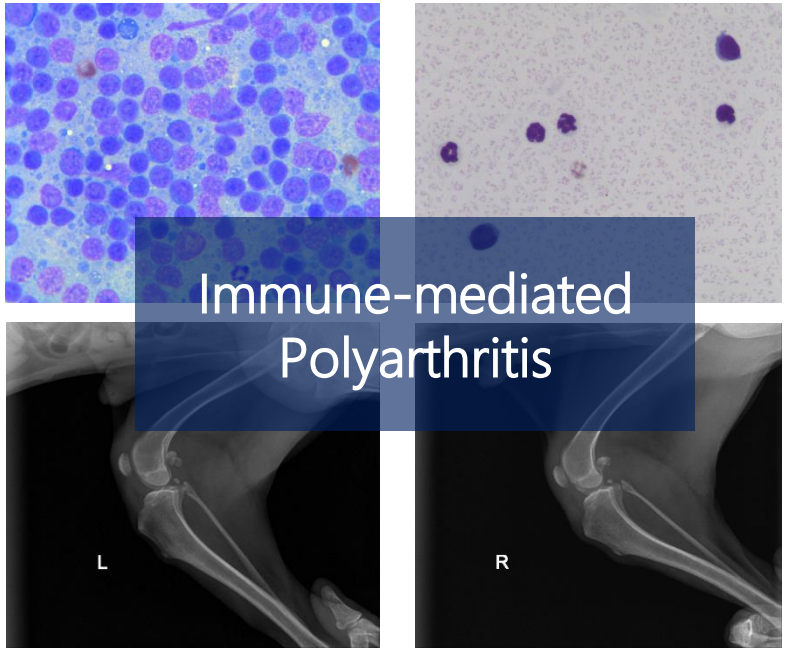
    ⇒ Not recovered even after continuing treatment

- Signs of pancreatitis?
- CRP elevation?
- cPL test?
- Cause of fever and CRP elevation?

Case Study – cPL/fPL

Case #2 (misdiagnosis)

- MDB
  - NCS except CRP elevation (127 mg/L)
  - **Urinalysis** : NRF
  - **Chest X-ray** : NRF
  - **Abdominal ultrasonography** : mild pancreatitis, sublumbar LN enlargement
- **Vcheck cPL :** 145 ng/mL (normal)



- Lymph node enlargement
- Vector-borne disease PCR : negative
- Synovial fluid cytology
- Radiography of forelimbs and hindlimbs
- Autoimmune panel (IDEXX)

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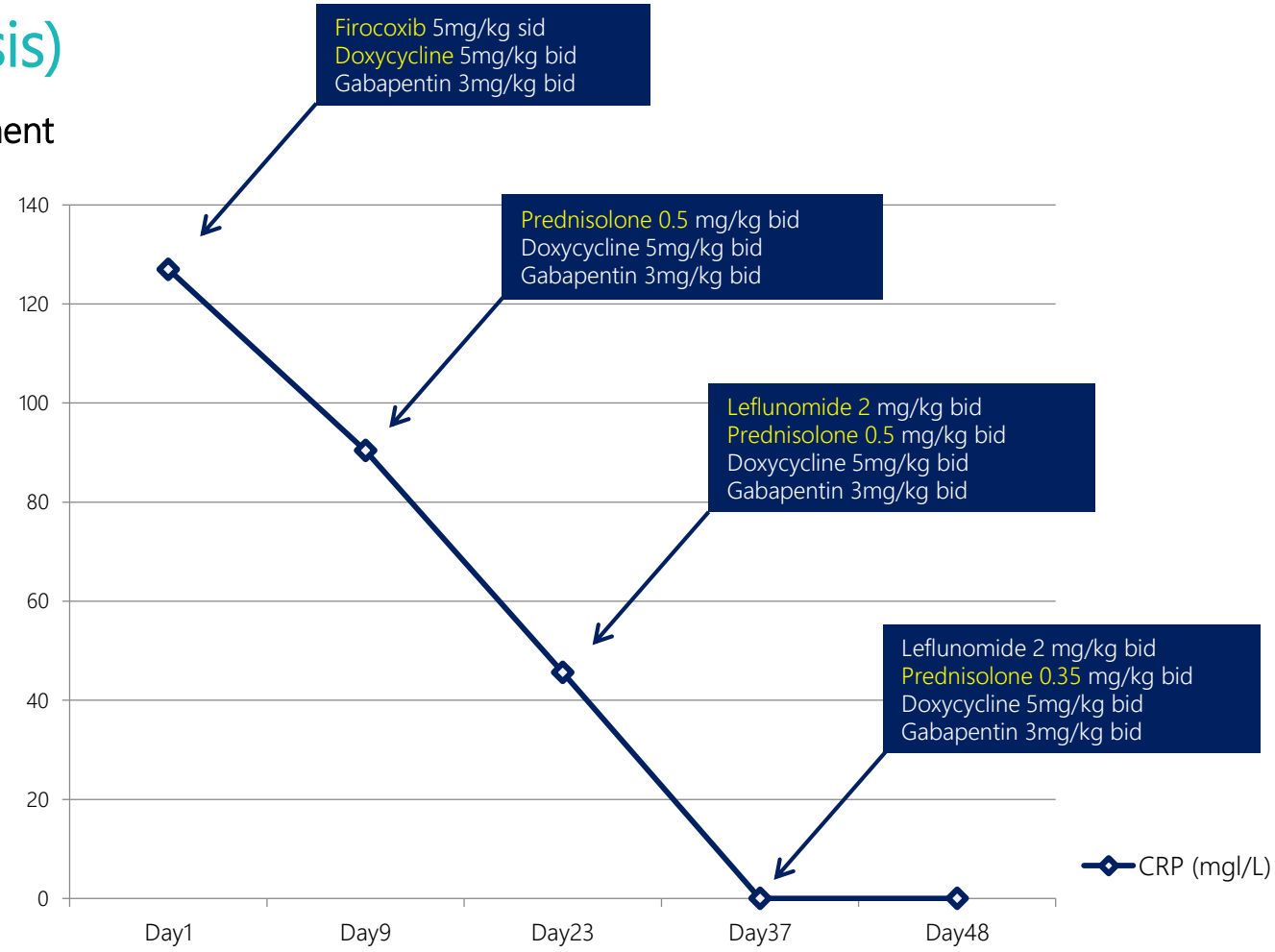
Case Study – cPL/fPL

Case #2 (misdiagnosis)

- CRP Changes during treatment



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Case Study – cPL/fPL

Case #3 (Treatment monitoring)

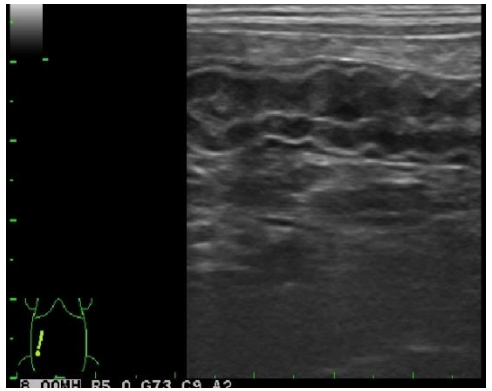
- Maltese, SF, 12 yrs
- HPI
  - GI signs – vomiting
  - Dyspnea
  - Dullness
  - Hypotension
  - Dehydration (7%)

- CRP 163 mg/L (*Reference: normal <20 mg/L)
- cPL > 2000 ng/mL (*Reference: normal <200 ng/ml)

  ⇒ Indicating severe inflammation

- Renal & hepatic parameters very high

  ⇒ Further evaluation on liver and kidney parenchyma required



▲ Ultrasonographic findings (Pancreatitis)

Date/Time : 2017-09-18 오전 11:14:45

Name	Unit	Min	Max	Result
cCRP	mg/L			163
cPL concentration	ng/ml	0	200	2000

Name	Unit	Min	Max	Result
WBC	10x9/L	6	17	7.2
RBC	10x12/L	5.5	8.5	6.65
Hemoglobin[Hb]	g/dL	12	18	15.7
Hematocrit[Hct]	%	37	55	45.3
MCV	fL	66	77	68.1
MCH	pg	19.9	24.5	23.6
MCHC	g/dL	32	36	34.7
Platelet	10x9/L	200	500	581
ALB	mg/dL	2.6	4	3
TP	g/dL	5.2	8.2	6.1
GLU	mg/dL	70	110	53
ALP	U/L	0	212	557
ALT	U/L	0	120	1100
TBIL	mg/dL	0	0.9	0.4
AMY	U/L	400	1500	3000
BUN	mg/dL	6	26	81.7
CREA	mg/dL	0	1.6	4
Ca	mg/dL	8.6	12	8.2
PHOS	mg/dL	2.5	6.8	13.8
Na	mmol/L	138	160	133
K	mmol/L	3.7	5.8	5.1

▲ Blood work

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Case Study – cPL/fPL

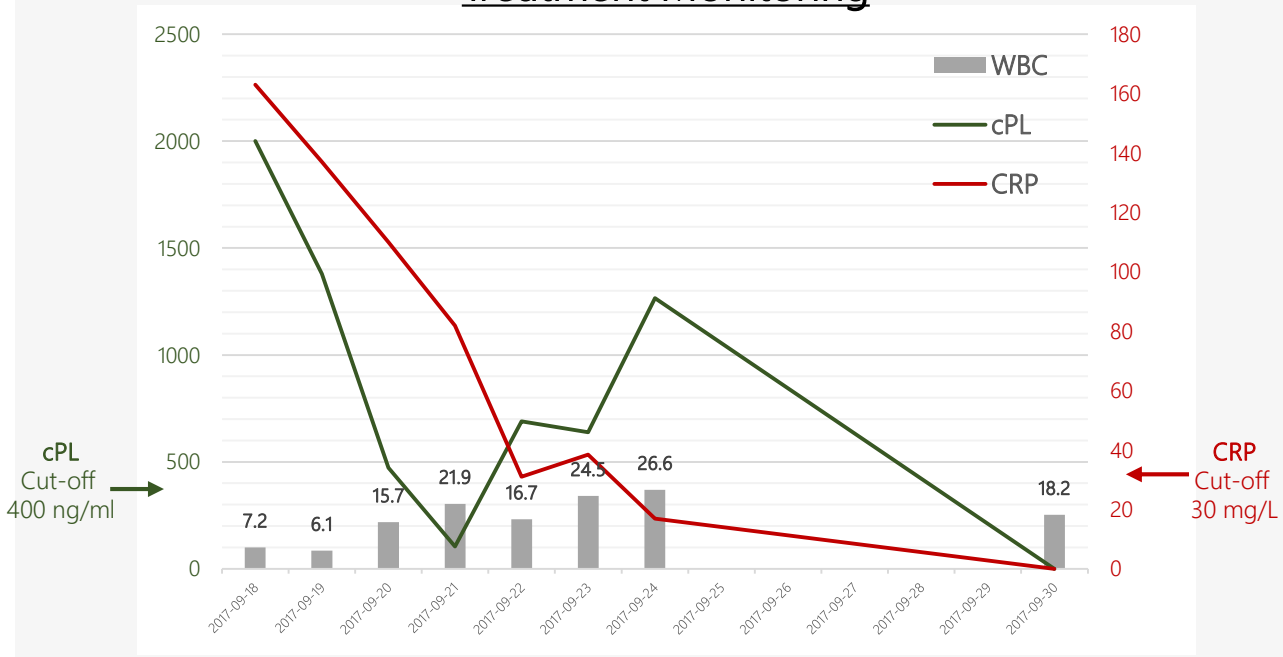
Case #3 (Treatment monitoring)

- Fluid Therapy
  - D/S 80ml/hr → until BP recover to 120
  - Plasma transfusion 20ml/kg IV for 4 hrs
  - H/D + Vit. B & C, 5% taurine

- **Maropitant** 0.1ml/kg SC SID
- **Pantoprazole** 1mg/kg IV BID
- **Cefazolin** 30mg/kg IV BID
- **Enoxaparin** 0.8mg/kg SC TID
- **Dexamethasone** 0.5mg/kg IV ONCE

- **Diet:** NPO

Treatment Monitoring



- Following the appropriate Tx, clinical signs disappeared.
- When the patient started to eat on 21st of Sep, cPL level was slightly increased and CRP level was decreased at the same time.
- **When the patient completely recovered, both CRP and cPL levels were decreased to the normal ranges.**

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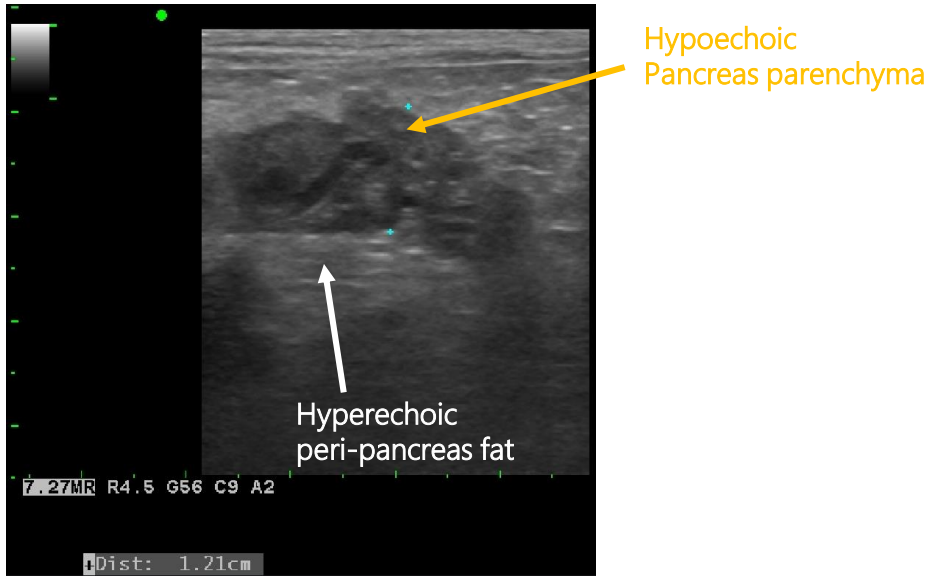
Case Study – cPL/fPL

Case #4 (Prognosis prediction)

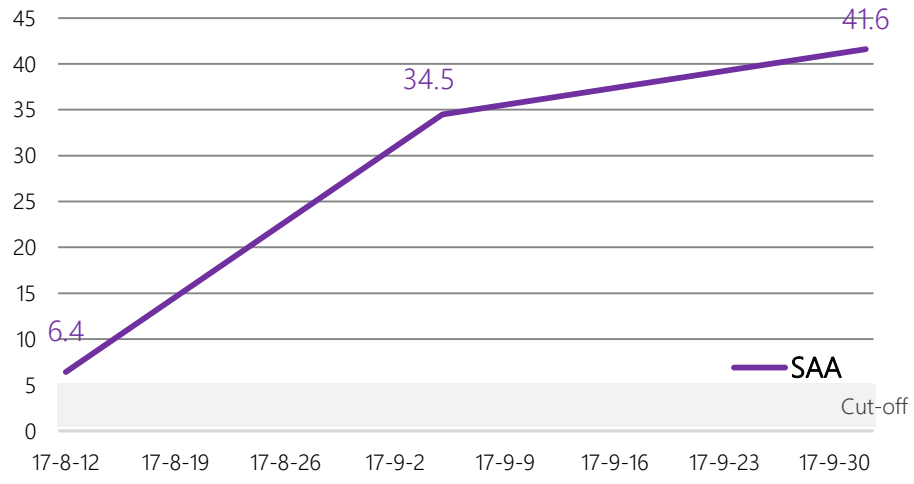
- Korean Short Hair, CM, 12 yrs
- HPI
  - Necrotizing / hemorrhagic pancreatitis
  - Pancreatic pseudocyst
- Diagnostic Imaging
  - Cystic change and peripancreatic inflammation (very severe)
  - Initially, no significant finding in gallbladder, intestines, etc



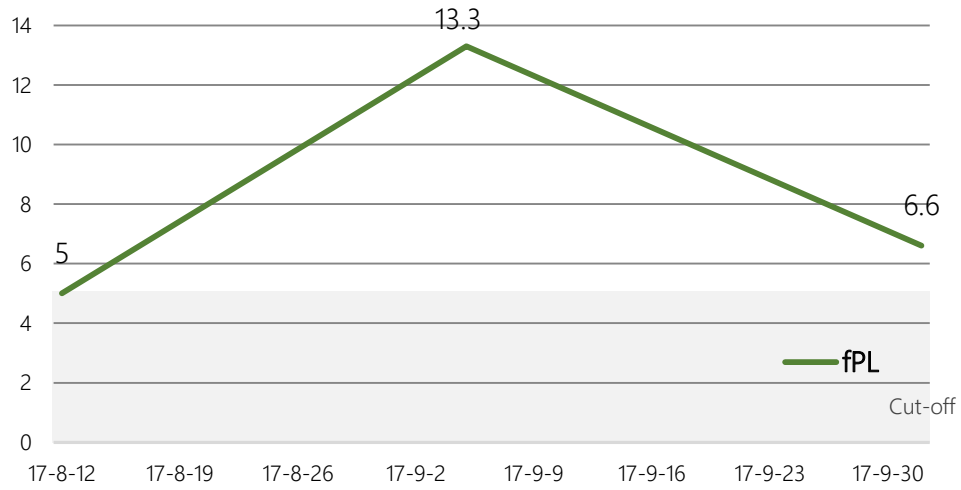
Case Study – cPL/fPL

Case #4 (Prognosis prediction)

- Although the cat ate well, fPL level was above the normal range.
- Based on the fPL concentration and the patient's age, the prognosis seemed poor. The cat eventually died.



▲ SAA Changes



▲ fPL Changes

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03 Product Introduction

Vcheck cPL & fPL

- Specifications
- Test Procedure
- Product Comparison
- Performance

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Product Introduction

- Specifications

  - Vcheck series for diagnosis of pancreatitis

Vcheck cPL 2.0		• **Species :** Dog • **Sample :** Serum 25 µl • **Testing Time :** 5 minutes • **Measurement :** Quantitative • **Measurement Range :** 50 – 2,000 ng/ml • **Storage Condition :** 1 - 30 °C
Vcheck fPL 2.0		• **Species :** Cat • **Sample :** Whole blood 50 µl, Plasma(EDTA)/Serum 25 µl • **Testing Time :** 15 minutes • **Measurement :** Quantitative • **Measurement Range :** 1 – 50 ng/ml • **Storage Condition :** 1 - 30 °C

BIONOTE

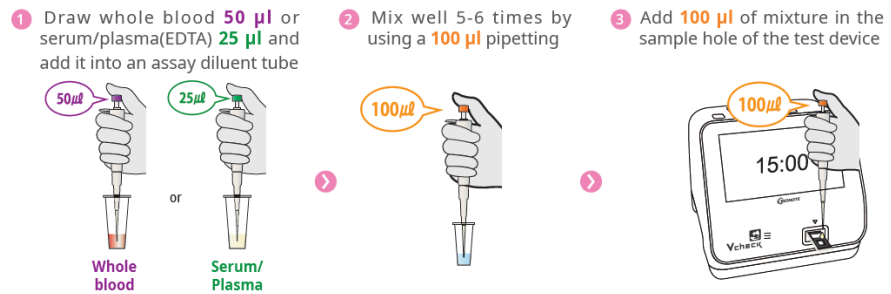
Product Introduction

- Test Procedure

✓ Vcheck cPL 2.0

< 200 ng/ml	200~400 ng/ml	> 400 ng/ml
Pancreatitis very unlikely	If clinical signs are present, treat appropriately and perform retest in 2 weeks. If the dog is asymptomatic or with mild symptoms, retesting should be performed after a month.	Consistent with pancreatitis

✓ Vcheck fPL 2.0



≤ 3.5 ng/ml	3.6~5.3 ng/ml	≥ 5.4 ng/ml
Pancreatitis very unlikely	If clinical signs are present, treat appropriately and perform retest in 2 weeks. If the cat is asymptomatic or with mild symptoms, retesting should be performed after a month.	Consistent with pancreatitis

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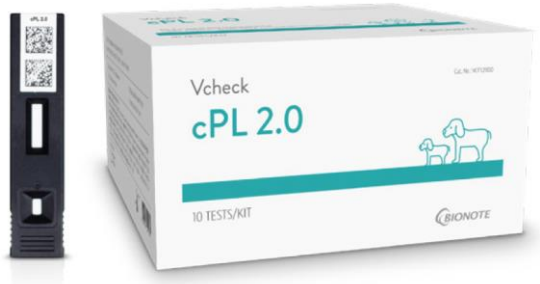
Product Introduction

- Product Comparison
  - Vcheck cPL 2.0



Test	BIONOTE	Company 'I'	
	Vcheck cPL 2.0	SNAP cPL	Spec cPL ELISA
Test Spot	In clinic	In clinic	Laboratory
Preparation time	Less than 1 min.	30 min. (incubation)	-
Reading time	5 min.	10 min.	2 - 3 days or more
Amount of sample	25 µl	100 µl	At least 500 µl
Type of sample	Serum	Serum	Serum
Measurement type	Quantitative	Semi-quantitative	Quantitative
Dynamic rage	50 – 2000 ng/ml	Not Applicable	50 – 2000 ng/mL
Storage temperature	1 - 30 °C	Refrigerated	Refrigerated

BIONOTE

Product Introduction

- Product Comparison

  - Vcheck fPL 2.0

Test	BIONOTE	Company 'I'	
	Vcheck fPL 2.0	SNAP fPL	Spec fPL ELISA
Test Spot	In clinic	In clinic	Laboratory
Preparation time	Less than 1 min.	30 min. (incubation)	-
Reading time	15 min.	10 min.	2 - 3 days or more
Amount of sample	Serum, plasma 25 µl Whole blood 50 µl	100 µl	At least 500 µl
Type of sample	Serum, Plasma, Whole blood	Serum	Serum
Measurement type	Quantitative	Semi-quantitative	Quantitative
Dynamic rage	1 – 50 ng/ml	Not Applicable	1-50 ng/ml
Storage temperature	1 - 30 °C	Refrigerated	Refrigerated

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Product Introduction

JOURNAL OF Veterinary Emergency AND Critical Care

Original Study

Journal of Veterinary Emergency and Critical Care **24**(2) 2014, pp 135–143
doi: 10.1111/vec.12158

Diagnostic accuracy of the SNAP and Spec canine pancreatic lipase tests for pancreatitis in dogs presenting with clinical signs of acute abdominal disease

Mark D. Haworth, BVSc; Giselle Hosgood, BVSc, MS, PhD, DACVS; Katrin L. Swindells, BVSc, DACVECC and Caroline S. Mansfield, BSc, BVMS, PhD, DECVIM

Table 6: Cross-tabulation of the agreement (κ) between SNAP cPL and specific canine pancreatic lipase (Spec cPL) for 36 dogs presented with signs of acute abdominal disease

	Spec cPL ≥ 200 μg/L	Spec cPL < 200 μg/L
SNAP positive	14	4
SNAP negative	0	18

κ = 0.78 (95% CI: 0.59–0.98).

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Product Introduction

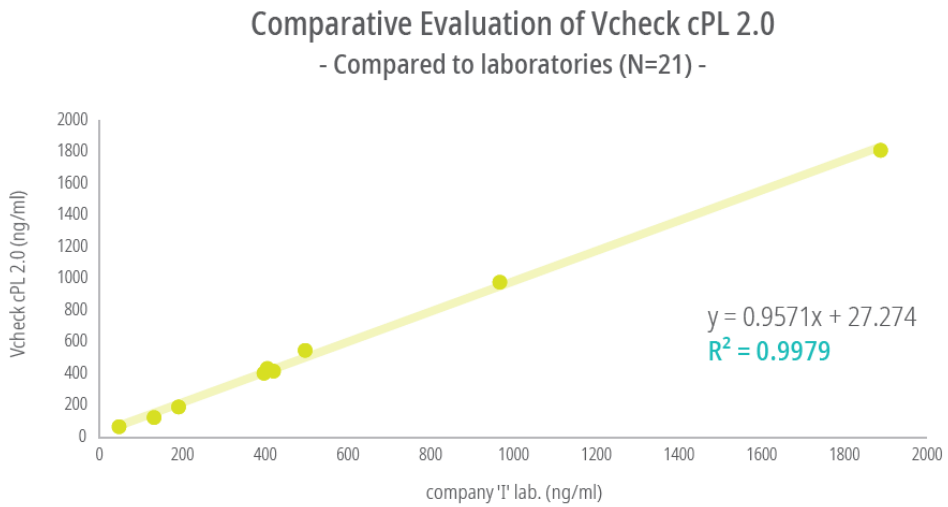
- **Performance** (Vcheck cPL 2.0)

Reproducibility CV < 15%

Accuracy Bias < 20%

✓ Strong correlation with laboratories

Vcheck cPL 2.0 has a high correlation (R^2 = 0.9979) with company 'I' laboratories.
This analyzer allows you to perform quantitative measurements for the accurate diagnosis easily in your clinics.



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Product Introduction

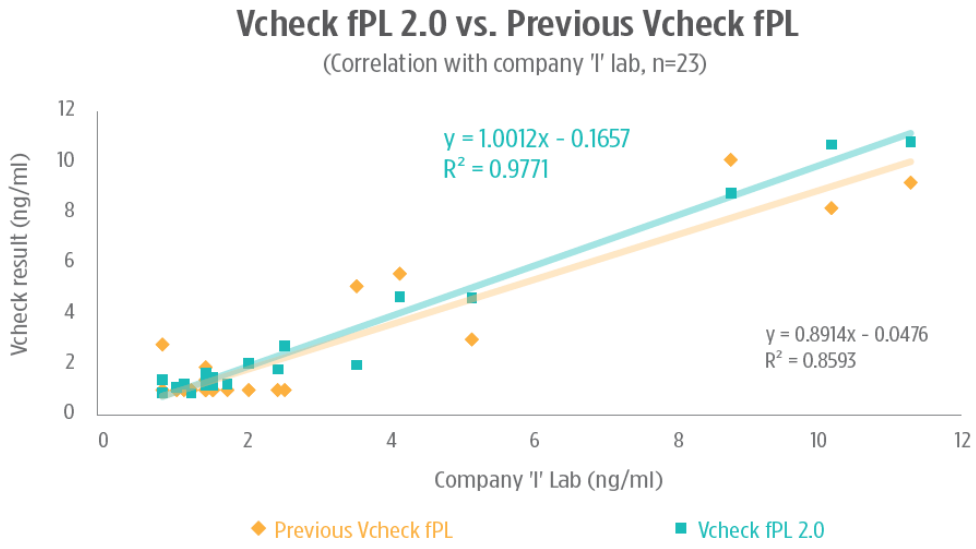
- **Performance** (Vcheck fPL 2.0)

Reproducibility CV < 15%

Accuracy Bias < 20%

✓ Greater accuracy at low concentrations

Stronger correlation (R^2=0.98) of Vcheck fPL 2.0 with company 'I' laboratory, compared to our existing products



*In case of using whole blood, it may affect the test results since each individual has different hematocrit levels (HCT; volume percentage of red blood cells) in blood. HCT levels less than 20% may cause falsely high values and HCT levels greater than 60% may cause falsely low values.

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Product Introduction

- Comparison of Vcheck, Spec, SNAP(cPL), Australia

✓ Study Results

Table 1. Vcheck vs Spec

		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 vs SNAP

		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 vs SNAP

		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.

✓ Correlation

= 95%

= 92.5%

= 87.5%

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Product Introduction

- Comparison of Vcheck, Spec cPL(IDEXX), Denmark

Measurement of cPL	(ng/ml)	Vcheck cPL (< 200 Normal, 200 – 400 Suspected, > 400 Abnormal)			
		Normal	Suspected	Abnormal	Sum
IDEXX (< 200 Normal, 201 – 399 Suspected, > 400 Abnormal)	Normal	19	0	0	19
	Suspected	0	1	0	1
	Abnormal	0	1	0	1
	Sum	19	2	0	21

Figure 2. Correlation between the results of Vcheck cPL and IDEXX cPL in canine samples (n=21)

Measurement of fPL	(ng/ml)	Vcheck fPL (≤ 3.5 Normal, 3.6-5.3 Suspected, ≥ 5.4 Abnormal)			
		Normal	Suspected	Abnormal	Sum
IDEXX (≤ 3.5 Normal, 3.6-5.3 Suspected, ≥ 5.4 Abnormal)	Normal	12	0	0	12
	Suspected	0	0	0	0
	Abnormal	1	0	1	2
	Sum	13	0	1	14

Figure 2. Correlation between the results of Vcheck fPL and IDEXX fPL in feline samples (n=14)

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Q&A

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Thank you

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