

Canine Pancreatic Lipase (cPL) Test Assay (Fluorescence immunochromatography)

Clinical Comparison Report

1 Purpose

To evaluate the consistency of the results of the Wondfo cPL test and IDEXX-SNAP cPL test in clinical.

2 Time

2023.04.03-2023.04.04

3 Materials

3.1 Reagents and Analyzer

	Wondfo	IDEXX
Product Name	cPL test assay	SNAP® cPL™
LOT No.	V40815201 A	FU676
Analyzer	YG-101	/

3.2 Samples

43 canine samples (EDTA anticoagulated plasma) collected from pet hospitals

4 Interpretation

4.1 Wondfo cPL result interpretation

Detection range: 50-2000 µg/L

< 200	Normal
200~400	Elevated
> 400	Pancreatitis

4.2 IDEXX cPL result interpretation

< 200	Sample spot is lighter than reference spot.	Normal
200~400	Sample spot is the same color as reference spot	Elevated
> 400	Sample spot is darker than reference spot	Pancreatitis

5 Comparison Methods

Since the Wondfo cPL test assay is quantitative and the IDEXX cPL test is qualitative, the interval agreement rate and positive/negative agreement rate of these two products are calculated. The results of normal, elevated and pancreatitis were used for secondary weighting (the difference between normal and elevated results was more important than that of elevated and pancreatitis results) Kappa analysis. And Kappa analysis was performed on the negative (<200 µg/L) and positive (>200 µg/L) test results.

6 Result

6.1 Test result

IDEXX	Wondfo	IDEXX	Wondfo
-	37.1	+	302.7
-	48.5	+	426.5
-	55.2	+	439.3
-	57.5	+	483.7
-	58.4	Elevated	523.0
-	62.2	+	531.3
-	65.4	+	532.5
-	78.6	+	548.1
-	89.3	Elevated	686.0
-	108.8	Elevated	766.5
-	119.2	+	834.5
-	120.4	+	882.6
-	141.0	+	918.2
-	170.5	+	1043.6
-	176.4	+	1046.8
-	186.5	Elevated	1195.3
-	202.0	+	1492.1
-	204.3	+	1661.2
-	422.7	+	1925.2
+	165.3	+	2070.5
Elevated	215.6	+	2119.9
+	266.6		

6.2 Agreement rate

6.2.1 Interval agreement rate and secondary weighting Kappa analysis

The results showed that the agreement rate was 84.2% for “normal” results, 20% for “elevated” results, and 84.2% for “pancreatitis” results. The weighted Kappa value

was 0.78947, which was greater than 0.75, indicating that the results of these two diagnostic methods were highly consistent.

Table: Interval agreement rate

cPL	Result	IDEXX		
		Normal	Elevated	Pancreatitis
Wondfo	Normal	16	0	1
	Elevated	2	1	2
	Pancreatitis	1	4	16
	Interval agreement rate	84.2%	20.0%	84.2%

Table: Weighted Kappa analysis

Weighted Kappa	0.78947
Standard error	0.079341
95% CI	0.63402~0.94493

6.2.2 Positive/negative agreement rate

“Normal” results are classified as negative, and “elevated” or “pancreatitis” results are classified as positive. The negative agreement rate of these two products was 84.2%, the positive agreement rate was 95.8%, and the Kappa value was 0.80931, which was greater than 0.75, indicating that these two diagnostic methods have a high consistency with positive/negative agreement rate.

Table: Positive/negative agreement rate

cPL	Result	IDEXX	
		-	+
Wondfo	-	16	1
	+	3	23
	Agreement rate	84.2%	95.8%

Table: Kappa analysis

Kappa	0.80931
Standard error	0.090354
95% CI	0.63222~0.98641

7 Conclusion

The results of 43 clinical samples showed that the interval agreement rate and

positive/negative agreement rate between Wondfo cPL and IDEXX cPL were high.