



Analytical Performance Evaluation Report

- ***VB1 Diagnosis Panel***
- ***VB1 Preanesthetic Panel***
- ***VB1 Liver Panel***
- ***VB1 Renal Panel***
- ***VB1 Diagnosis Plus Panel***



Albumin (ALB)
Alkaline Phosphatase (ALP)
Alanine Aminotransferase (ALT)
Amylase (AMY)
Aspartate Aminotransferase (AST)
Blood Urea Nitrogen (BUN)
Chloride (Cl)
Creatinine (CREA)
Glucose (GLU)
Potassium (K)
Sodium (Na)
Total Bilirubin (TBIL)
Total Protein (TP)
Calcium (Ca)
Phosphorus (PHOS)

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Analytical Performance Evaluation Report

Revise date: 2014.02

1. Dynamic range

Test Item	Dynamic Range		Dynamic Range (SI Unit)	
ALB	2.0 - 8.0	g/dL	20 - 80	g/L
ALP	41 - 2000	U/L	41 - 2000	U/L
ALT	30 - 1100	U/L	30 - 1100	U/L
AMY	22 - 3000	U/L	22 - 3000	U/L
AST	30 - 1000	U/L	30 - 1000	U/L
BUN	2.0 - 140.0	mg/dL	0.7 - 50.0	mmol urea/L
Cl	70 - 140	mmol/L	70 - 140	mmol/L
CREA	0.6 - 20.0	mg/dL	53 - 1768	μmol/L
GLU	30 - 550	mg/dL	1.7 - 30.5	mmol/L
Na	110 - 175	mmol/L	110 - 175	mmol/L
K	1.5 - 8.5	mmol/L	1.5 - 8.5	mmol/L
TBIL	0.4 - 30.0	mg/dL	7.0 - 513.0	μmol/L
TP	1.5 - 10.0	g/dL	15 - 100	g/L
Ca	4.0 - 15.0	mg/dL	1.0 - 3.8	mmol/L
PHOS	0.1 - 20.0	mg/dL	0.03 - 6.45	mmol/L

2. Analytical Specificity (Interference study)

Physiological interferences in blood include hemolysis, icterus, and lipemia. For every test item, 2 Levels serum pool supplemented with known concentrations of the endogenous substances were used for the testing. Significant interference is defined as a >20% shift in the test result. (Note: Highest tested concentration for Hemoglobin: 600 mg/dL; Bilirubin (unconjugated): 62.5 mg/dL, Bilirubin (conjugated): 57.5 mg/dL; Intralipid: 0.55%)

Test Item	Substance concentration with interferences of less than 20%			
	Hemoglobin	Bilirubin (unconjugated)	Bilirubin (conjugated)	Intralipid
ALB	300 mg/dL	62.5 mg/dL	57.5 mg/dL	0.2%
ALP	600 mg/dL	25.9 mg/dL	57.5 mg/dL	0.1%
ALT	600 mg/dL	36.7 mg/dL	18.9 mg/dL	0.1%
AMY	600 mg/dL	35.2 mg/dL	19.4 mg/dL	0.2%
AST	300 mg/dL	42.1 mg/dL	22.3 mg/dL	0.1%
BUN	500 mg/dL	42.1 mg/dL	29.3 mg/dL	0.43%
Cl	300 mg/dL	22.5 mg/dL	---	0.1%

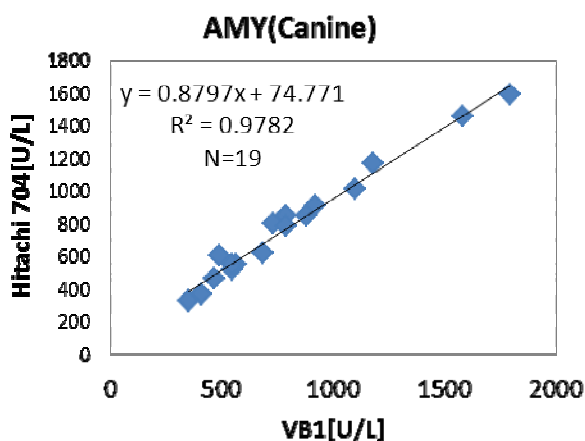
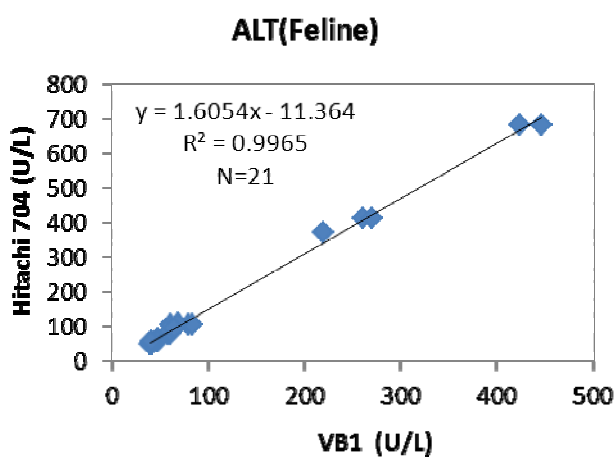
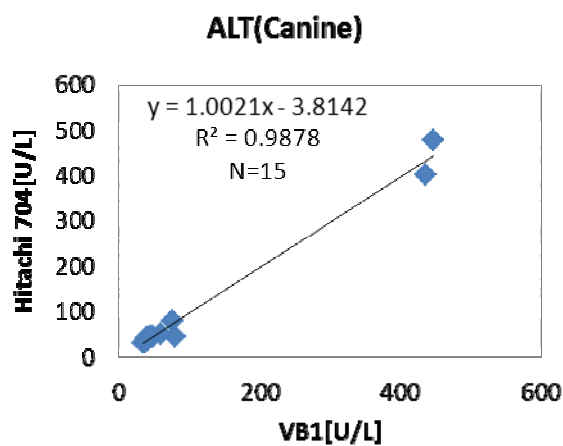
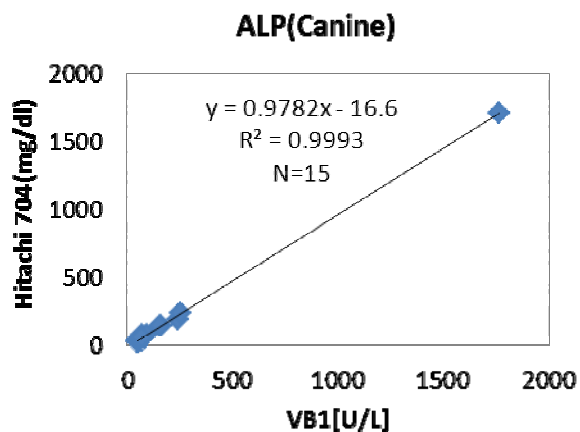
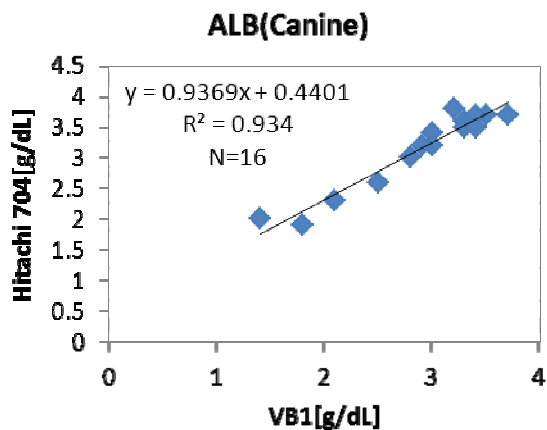
Test Item	Substance concentration with interferences of less than 20%			
	Hemoglobin	Bilirubin (unconjugated)	Bilirubin (conjugated)	Intralipid
CREA	200 mg/dL	25.9 mg/dL	---	0.17%
GLU	600 mg/dL	62.5 mg/dL	57.5 mg/dL	0.3%
Na	600 mg/dL	43.3 mg/dL	33.5 mg/dL	0.4%
K	100 mg/dL	33.5 mg/dL	22.8 mg/dL	0.15%
TBIL	600 mg/dL	---	---	0.1%
TP	300 mg/dL	62.5 mg/dL	57.5 mg/dL	0.2%
Ca	600 mg/dL	56.3 mg/dL	57.5 mg/dL	0.3%
PHOS	500 mg/dL	42.1 mg/dL	57.5 mg/dL	0.17%

3. Method Comparison (fresh whole blood)

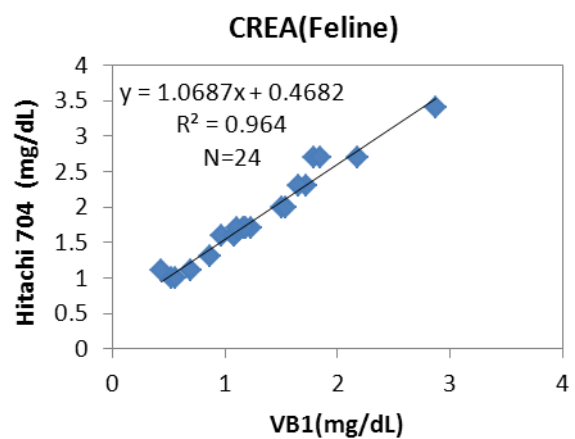
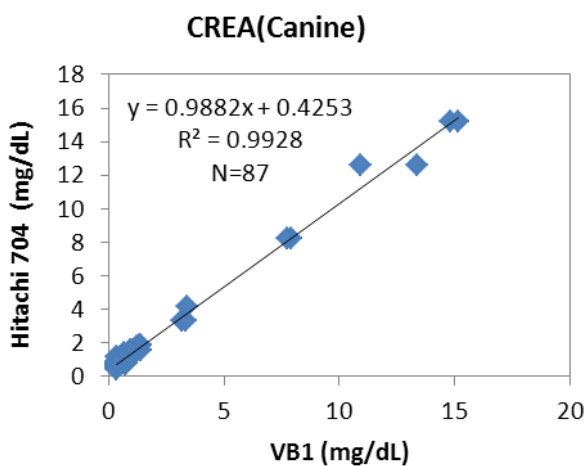
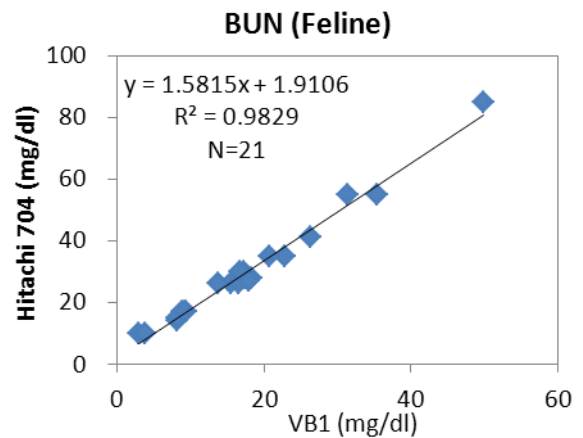
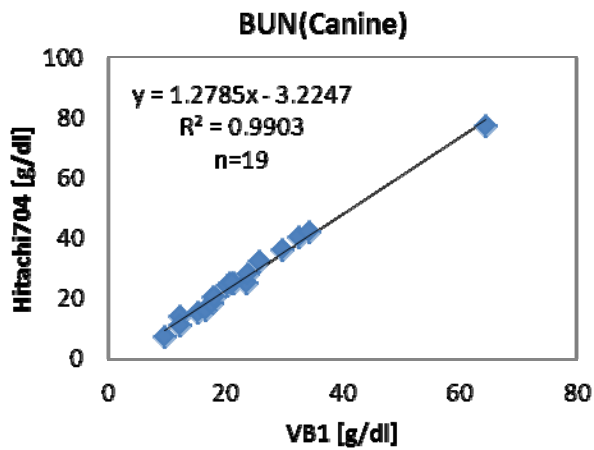
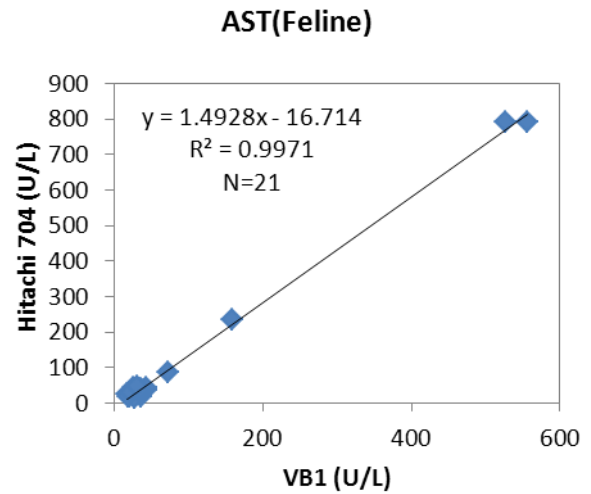
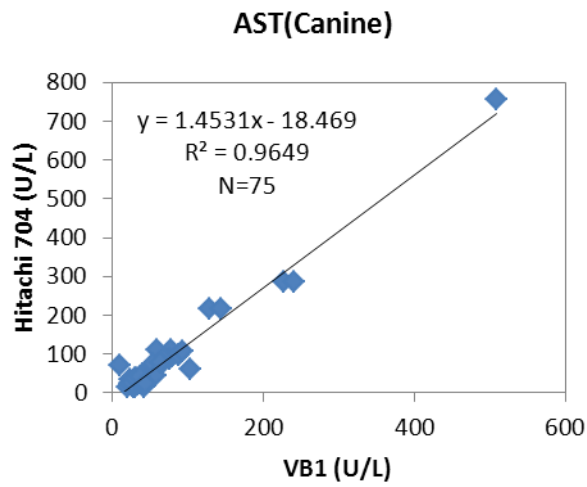
This study was implemented for some kind of markers. The HITACHI 704 and/or SIMENS ADVIA 1800 were used as comparative method in the study. The tests are performed by using the same clinical sample that whole blood in skyla and plasma in HITACHI 704 / SIMENS ADVIA 1800. Correlation between two methods can be determined through statistical analysis.

Marker		R ²	Slope	Intercept	Sample No.	Sample Range
ALB	Canine	0.9340	0.9369	0.4401	16	1.9-3.8 g/dL
ALP	Canine	0.9993	0.9782	-16.6	15	31-1708 U/L
ALT	Canine	0.9878	1.0021	-3.8142	15	32-478 U/L
	Feline	0.9965	1.6054	-11.364	21	50-681 U/L
AMY	Canine	0.9782	0.8797	74.771	19	367-1795 U/L
AST	Canine	0.9649	1.4531	-18.469	75	14-756U/L
	Feline	0.9971	1.4928	-16.714	21	18-792 U/L
BUN	Canine	0.9903	1.2785	-3.2247	19	7-77 mg/dL
	Feline	0.9829	1.5815	1.9106	21	10-85 mg/dL
CREA	Canine	0.9522	0.6993	0.3553	19	0.4-15.2 mg/dL
	Feline	0.9640	1.0687	0.4682	24	1.1-3.4 mg/dL
GLU	Canine	0.9616	1.0897	3.2265	79	8-332 mg/dL
	Feline	0.9818	1.0473	17.431	23	79-416 mg/dL
TP	Canine	0.9201	1.089	-0.2106	19	5.6-9.3 g/dL
	Feline	0.9737	1.0968	-0.1905	23	6.7-9.6 g/dL
Ca	Canine	0.9199	0.8846	1.4703	52	8.1-14.5 mg/dL
PHOS	Canine	0.9182	1.0189	-0.0442	45	0.8-7.6 mg/dL

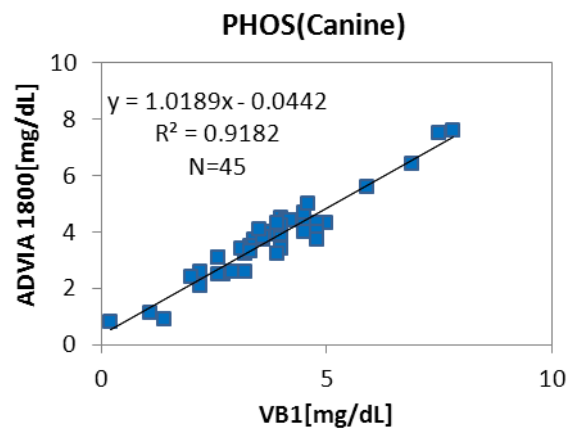
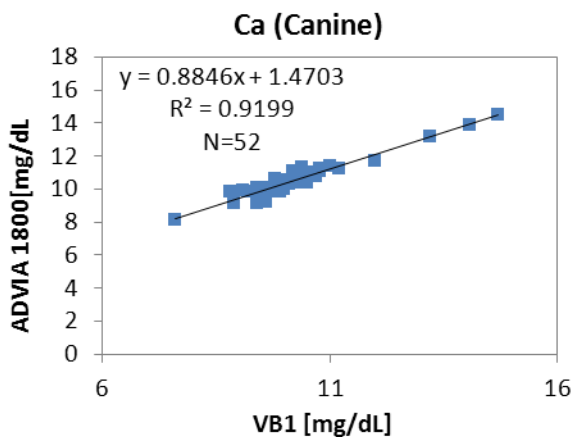
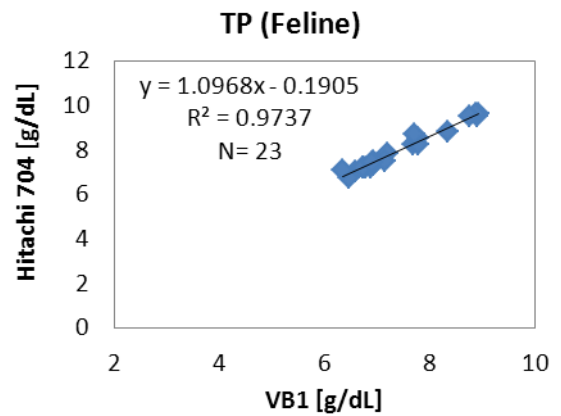
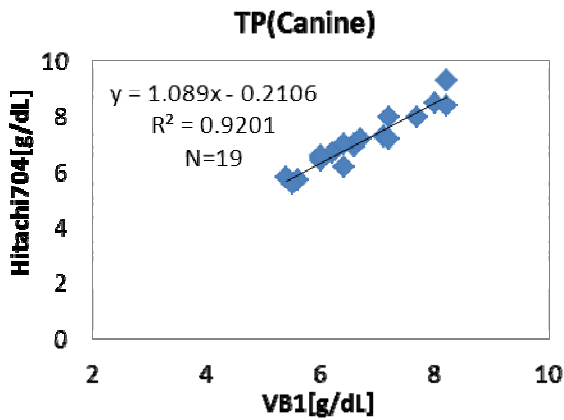
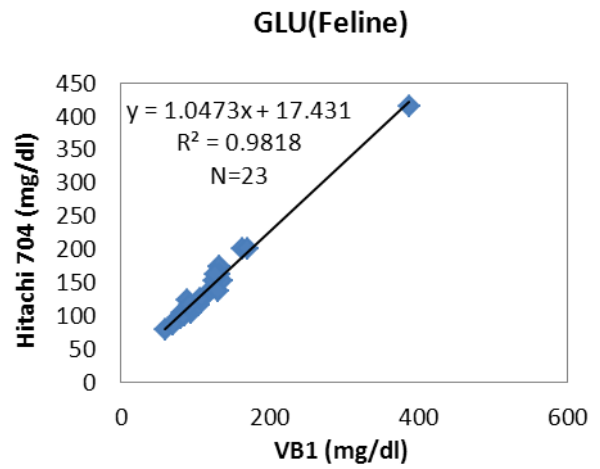
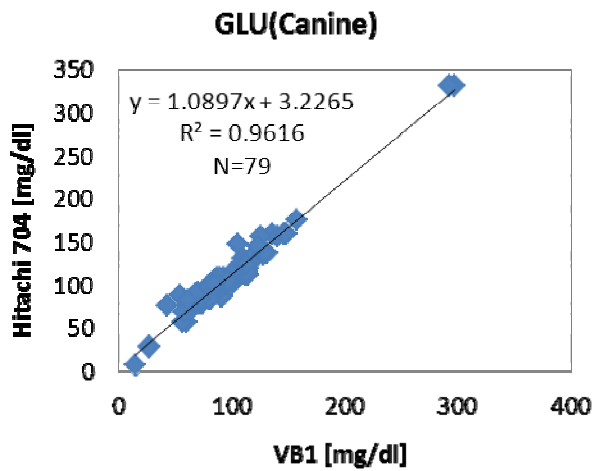
Statistical analysis results of method comparison study for whole blood sample from Dogs and Cats.



Statistical analysis results of method comparison study for whole blood sample from Dogs and Cats.



Statistical analysis results of method comparison study for whole blood sample from Dogs and Cats.

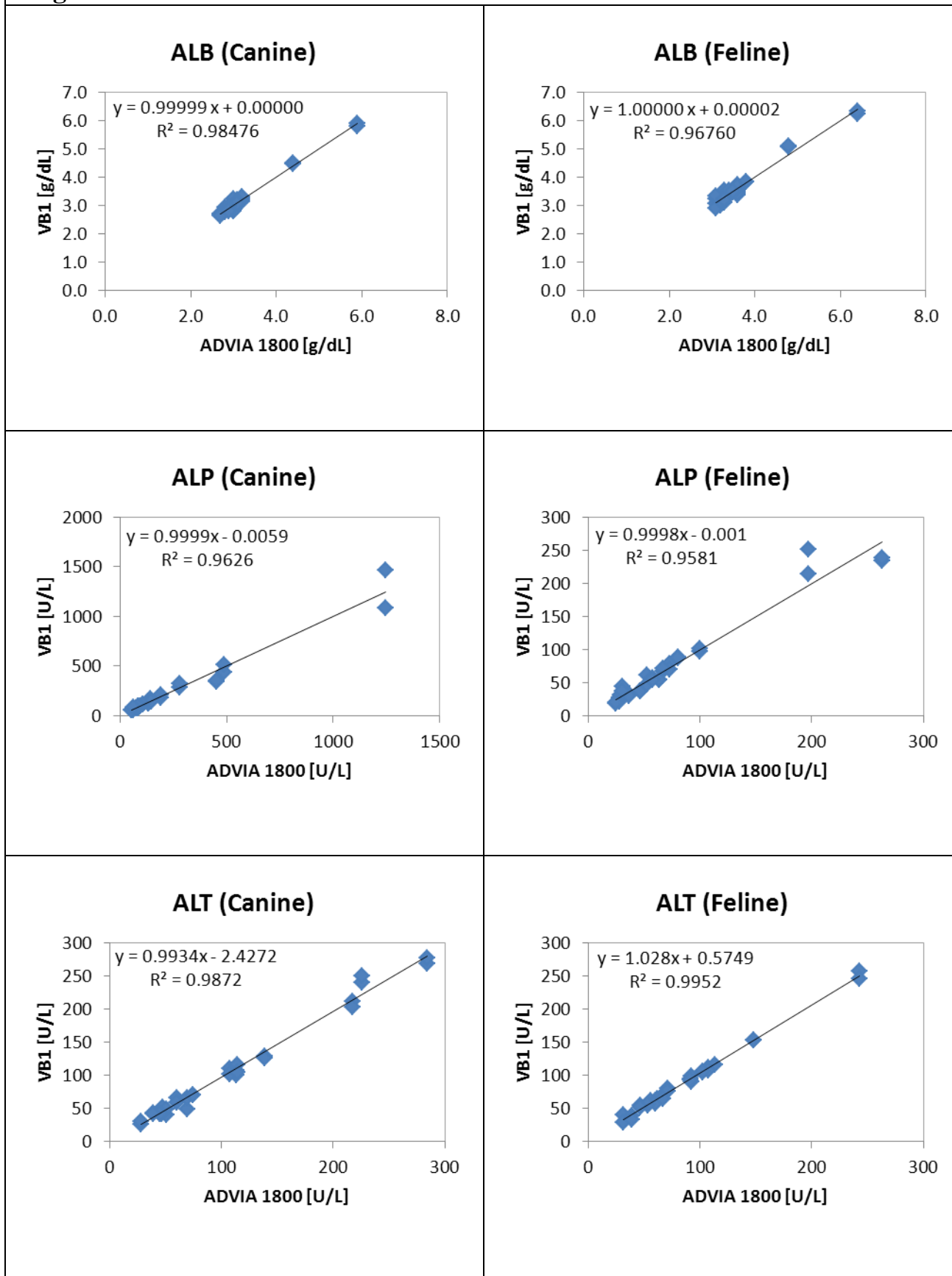


4. Method Comparison (Plasma; centrifuged sample from fresh whole blood)

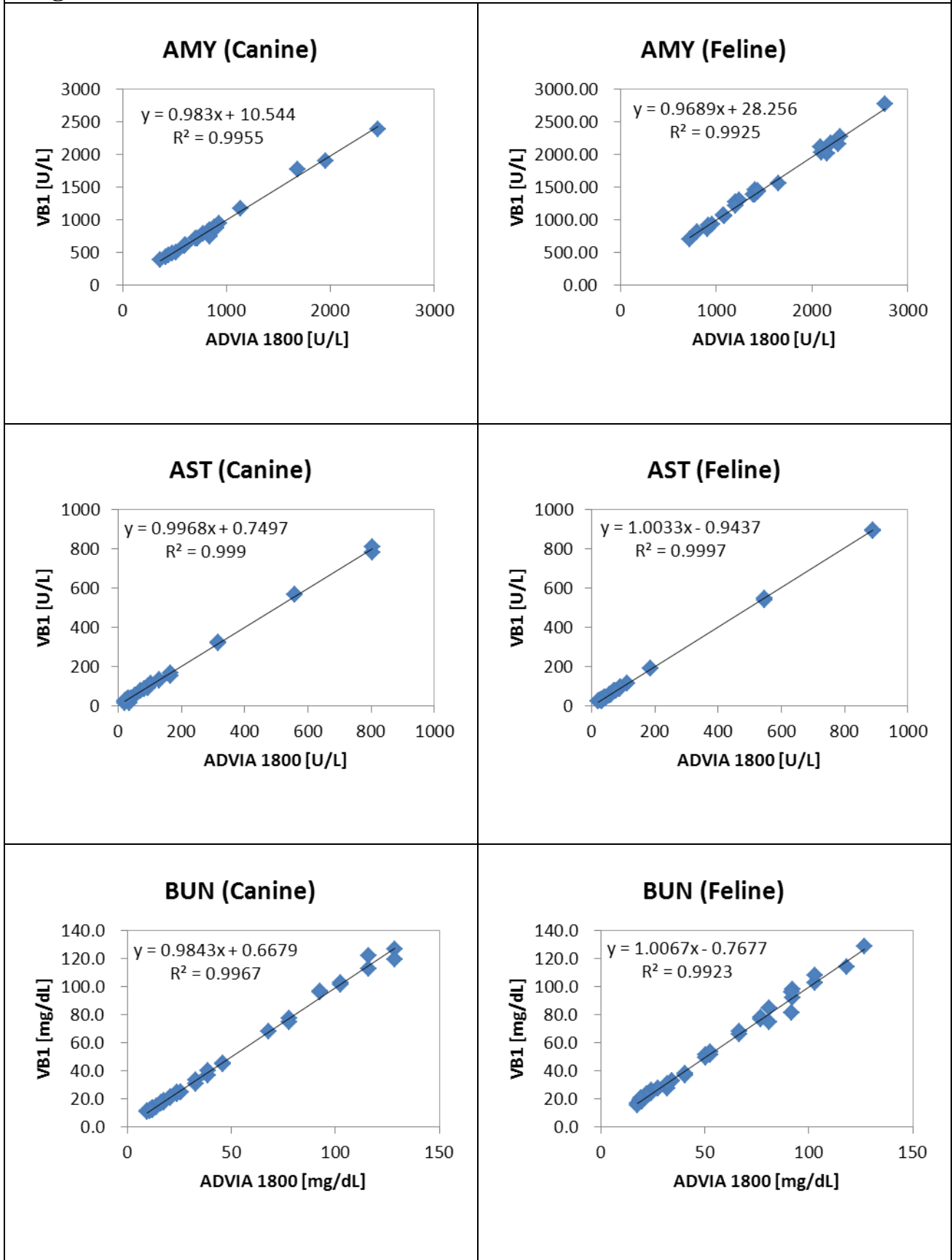
The SIMENS ADVIA 1800 was used as comparative method in the study. The tests are performed by using the same clinical plasma sample for two methods. Correlation between two methods can be determined through statistical analysis.

Marker		R ²	Slope	Intercept	Sample No.	Sample Range
ALB	Canine	0.9848	0.9999	0.0000	38	2.7-5.9 g/dL
	Feline	0.9676	1.0000	0.0000	38	3.1-6.4 g/dL
ALP	Canine	0.9626	0.9999	-0.0059	32	53-1246 U/L
	Feline	0.9581	0.9998	-0.0010	32	24-263 U/L
ALT	Canine	0.9872	0.9934	-2.4272	31	28-284 U/L
	Feline	0.9951	1.0290	0.2758	32	31-243 U/L
AMY	Canine	0.9955	0.9830	10.544	20	368-2454 U/L
	Feline	0.9925	0.9689	28.25	24	724-2759 U/L
AST	Canine	0.9990	0.9968	0.7497	38	22-803 U/L
	Feline	0.9997	1.0033	-0.9437	38	22-891 U/L
BUN	Canine	0.9967	0.9843	0.6679	42	10.7-128.4 mg/dL
	Feline	0.9923	1.0067	-0.7677	40	17.5-126.9 mg/dL
Cl	Canine	0.9853	1.0192	-1.3378	19	66-143 mmol/L
	Feline	0.9839	1.0000	0.00005	21	70-142 mmol/L
CREA	Canine	0.9968	1.0526	-0.0305	38	0.47-16.93 mg/dL
	Feline	0.9928	1.0498	-0.2650	38	1.2-17.65 mg/dL
GLU	Canine	0.9953	1.0000	0.00892	43	78-558 mg/dL
	Feline	0.9957	0.9956	2.1761	44	93-549 mg/dL
Na	Canine	0.9635	0.9999	0.0034	21	109-175 mmol/L
	Feline	0.9696	0.9999	0.0000	21	107-176 mmol/L
K	Canine	0.9634	0.9513	0.1877	24	2.1-5.6 mmol/L
	Feline	0.9634	0.9513	0.1877	24	2.1-5.6 mmol/L
TBIL	Canine	0.9970	0.9237	0.1946	35	0.1-31.2 mg/dL
	Feline	0.9957	0.9285	0.2412	26	0.1-31.2 mg/dL
TP	Canine	0.9603	0.9999	0.0000	38	5.2-9.5 g/dL
	Feline	0.9883	0.9999	0.0000	38	6.3-10.3 g/dL
Ca	Canine	0.9945	1.0006	-0.0095	19	7.3-16.4 mg/dL
	Feline	0.9689	0.9814	0.1209	19	7.1-16.4 mg/dL
PHOS	Canine	0.9434	0.9434	0.2678	30	2.7-13.2 mg/dL
	Feline	0.9369	0.9369	0.3763	32	3.3-11.1 mg/dL

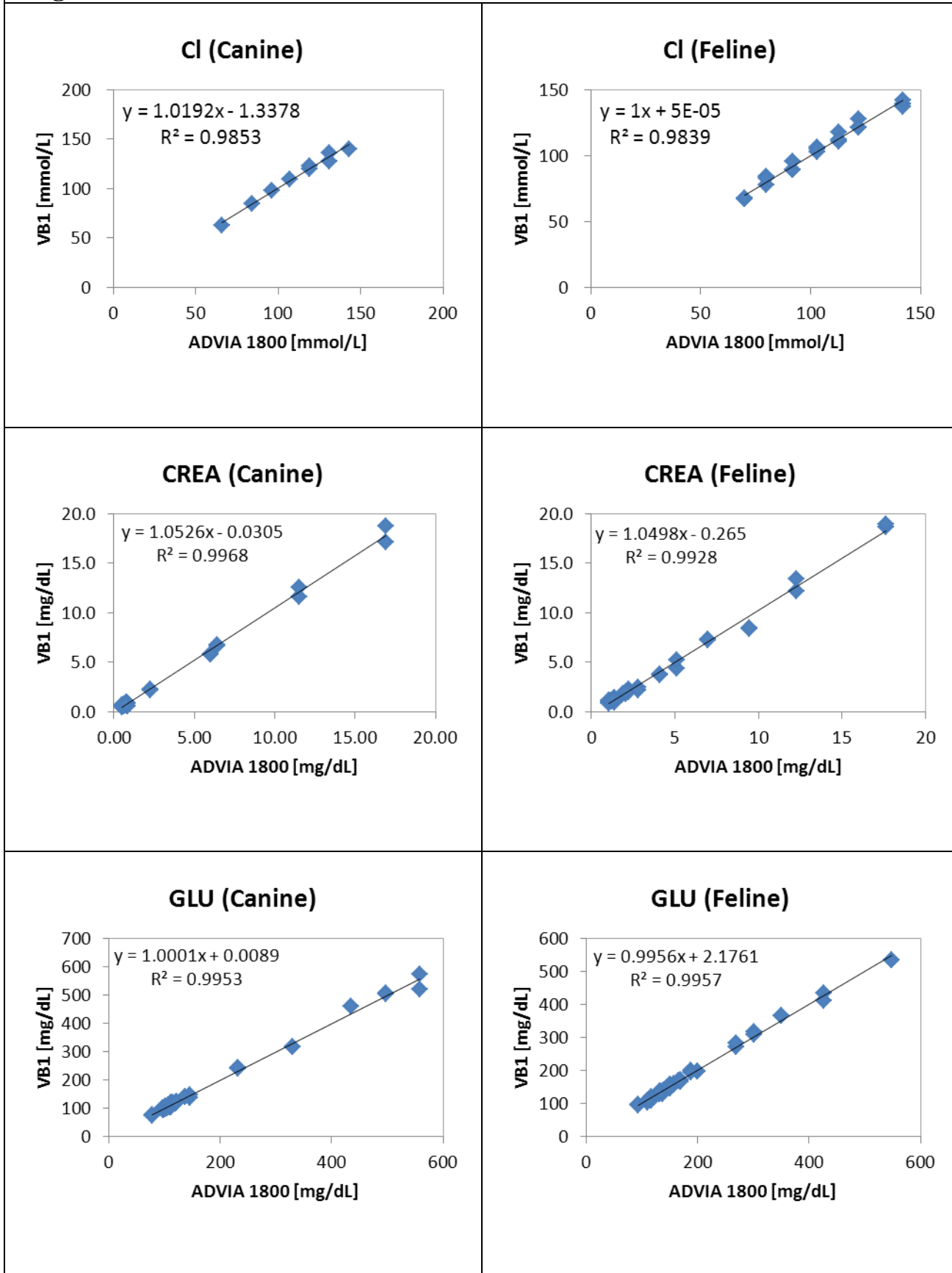
Statistical analysis results of method comparison study for plasma sample from Dogs and Cats.



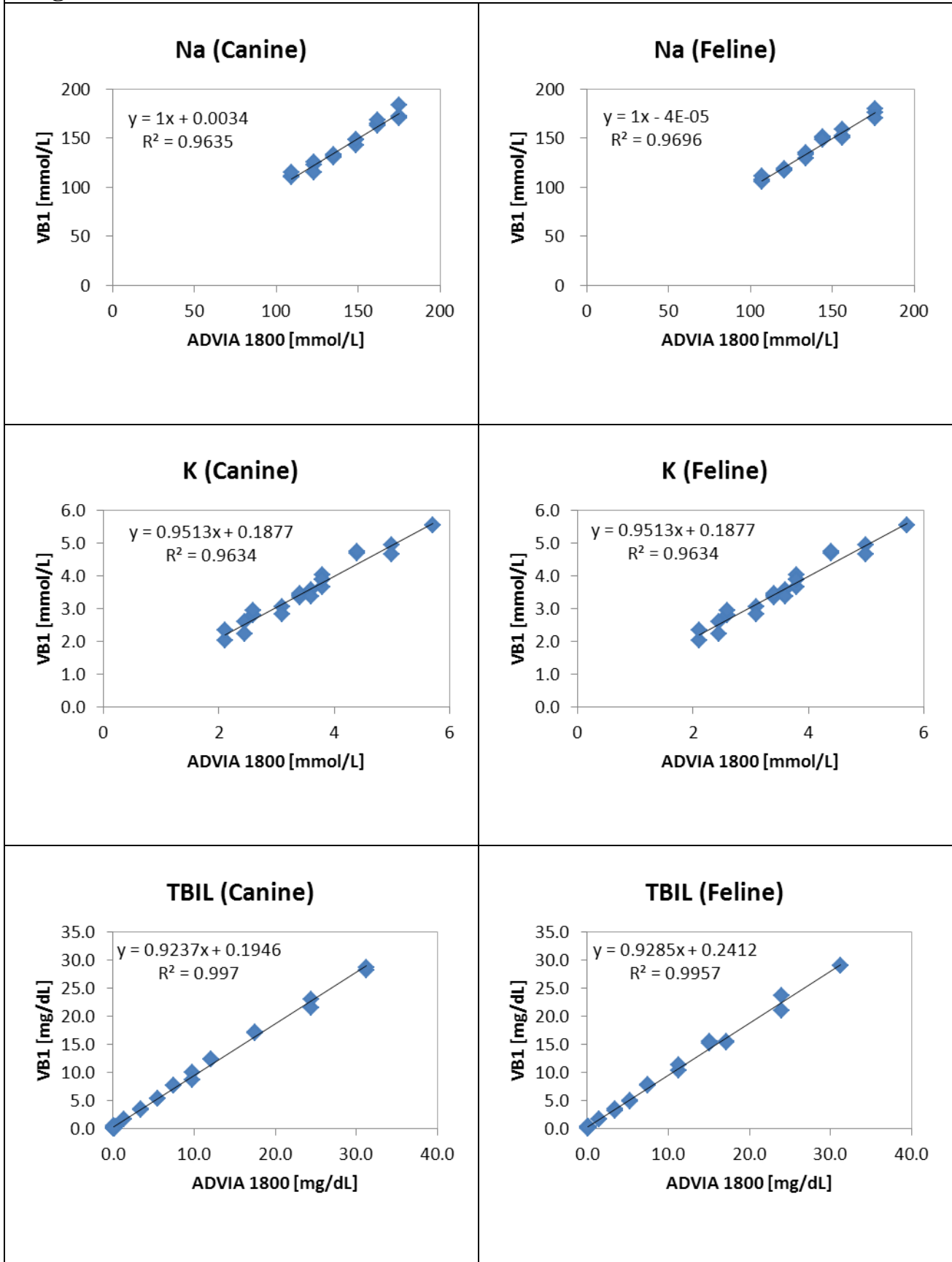
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