TECHNICAL BULLETIN

InCoag PT/APTT: Canine and Feline Performance & Reliability

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InCoag Coagulation Analyzer

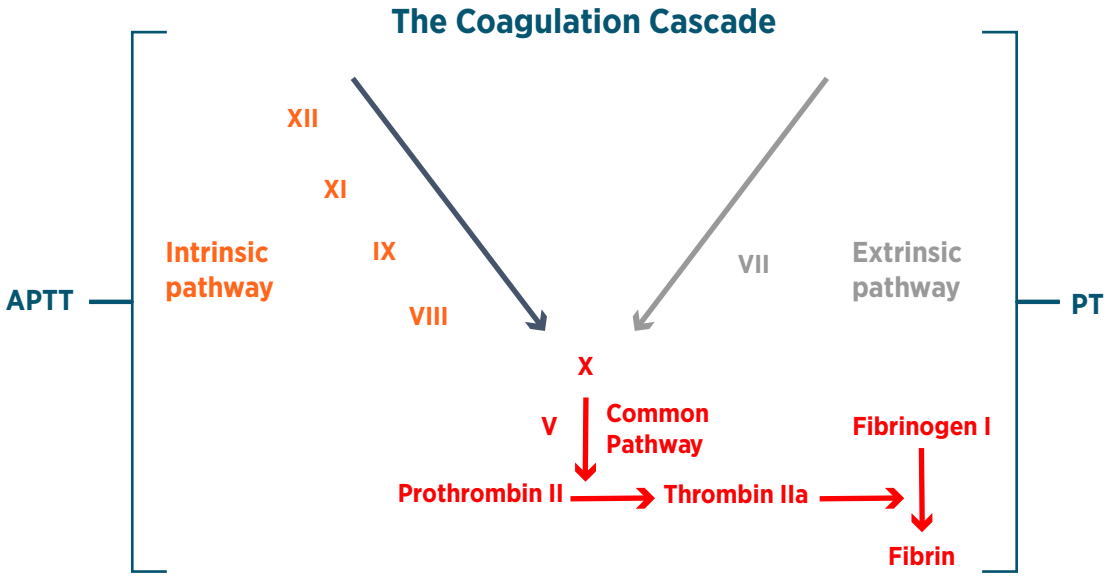
Introduction

The InCoag Coagulation Analyzer is a state-of-the-art, point-of-care diagnostic analyzer providing rapid assessment of the secondary system of blood coagulation for dogs and cats.

Hemostasis refers to a group of intricate, balanced physiologic processes that maintain the free flow of blood within vessels while also allowing the rapid formation of platelet plugs to seal injured vessels to ensure appropriate blood flow without bleeding. Normal hemostasis is dependent on the interactions of several major components including platelets, clotting factors, and blood vessels.[1] If one or more components of hemostasis is abnormal, hemorrhage or inappropriate clotting could occur. Laboratory testing of the different components of hemostasis is available to help diagnose and monitor different disease states that can result in abnormal hemostasis.

Hemostasis is sub-divided into primary and secondary hemostasis (coagulation). Activation of primary hemostasis through blood vessel injury results in the formation of a vascular adherent platelet plug. Secondary hemostasis stabilizes the platelet plug by creating a fibrin mesh through the activation of soluble, circulating clotting factors. An imbalance in this process results in coagulopathy or bleeding disorder.[2]

For clinical decision-making purposes, secondary hemostasis can be thought of as a chain of activations in three pathways: the intrinsic, extrinsic, and common pathways.[2]



The InCoag provides rapid testing of both the extrinsic pathway via Prothrombin Time (PT) and the intrinsic pathway via Activated Partial Thromboplastin Time (APTT) from a single 100 µl citrated whole blood (CWB) sample. After filling the sample port, the CWB is drawn into reagent coated microchannels. The sample is then circulated in these channels to ensure proper reagent-sample mixing. While this is occurring, sample pressure and oscillation rate is measured to determine PT and APTT values.

A series of studies were performed to investigate the performance of the InCoag. Precise and accurate assessment of your patient's PT and APTT are provided by the InCoag. This technical summary of the InCoag includes the evaluation of:

- Precision performance studies of the InCoag
- Canine method comparison
- Feline method comparison

Precision Performance Studies of the InCoag[3]

This study was conducted to assess the precision performance of the InCoag veterinary point-of-care coagulation analyzer using control material with normal and prolonged coagulation times.

Materials & Methods

The precision performance of the InCoag citrated whole blood PT/APTT cartridge was measured using bilevel control material.[4] Bio-Rad® control material Level 1 was used to test precision as a normal control and Bio-Rad® control material Level 3 was used as the abnormal control material. A volume of 100 µl of each level of control material was used for each run. Runs were randomized across 2 different instruments and 2 different operators.

Results

The mean result of 12 runs of Level 1 control material for PT was 21.4 +/- 1.3 seconds with a coefficient of variation (CV%) of 6.01%. The mean result of 12 runs of Level 1 control material for APTT was 40.2 +/- 1.6 seconds with a coefficient of variation of 4.09%. The mean result of 11 runs of Level 3 control material for PT was 33.9 +/- 1.5 seconds with a coefficient of variation of 4.38%. The mean result of 12 runs of Level 3 control material for APTT was 71.80 +/- 3.04 seconds with a coefficient of variation of 4.24%.

Precision Performance Results

Level 1	PT (sec)	APTT (sec)
MEAN	21.4	40.2
SD	1.3	1.6
CV%	6.01%	4.09%

Level 3	PT (sec)	APTT (sec)
MEAN	33.9	71.80
SD	1.5	3.04
CV%	4.38%	4.24%

SD standard deviation; CV% coefficient of variation.

The precision performance for PT and APTT measured with CWB cartridges with both normal and prolonged control material was deemed acceptable. Additionally, these values compare favorably with both published standards for coagulation testing and published studies of veterinary instruments.[5-8]

Canine Method Comparison[9]

Materials & Methods

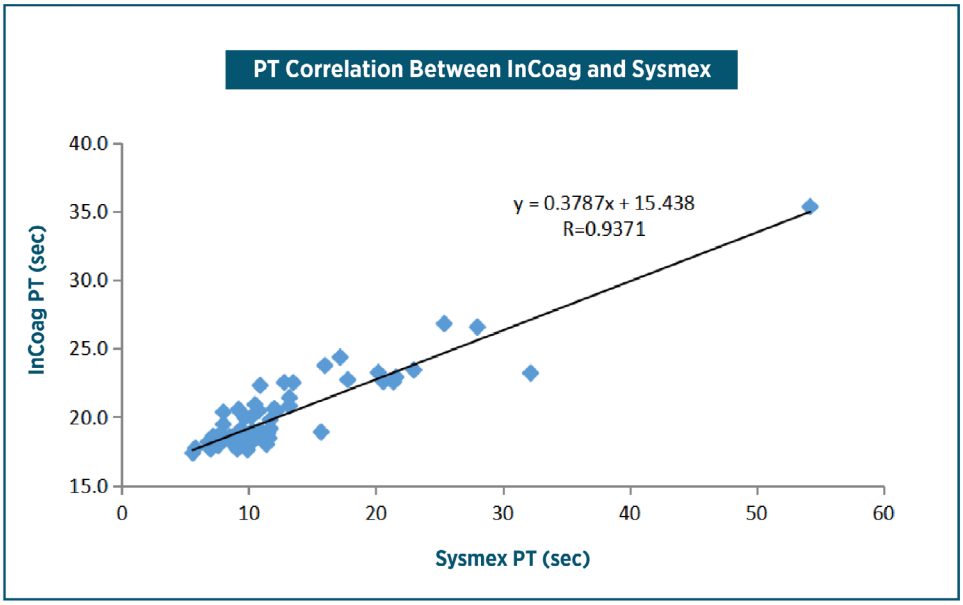
A total of 50 CWB samples were obtained from client owned dogs of 18 different breeds. Samples were collected from dogs with and without coagulopathies. These samples were transferred into the manufacturer validated citrated tubes after venipuncture with a 3 mL syringe and butterfly catheter. An additional 24 samples were spiked with unfractionated heparin (UFH) in varying amounts to mimic abnormal coagulation times. Each CWB sample was run on two InCoag analyzers simultaneously, obtaining values for PT and APTT. Each sample was then centrifuged to yield citrated plasma and then run on one Sysmex® CA-1500 coagulation reference analyzer to generate PT and APTT values for method comparison.

Results

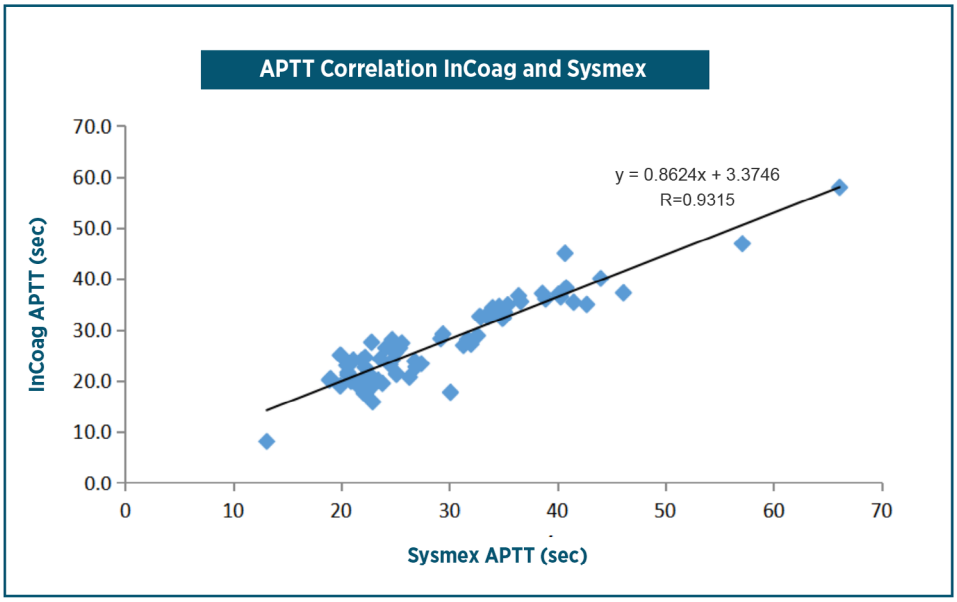
The results from 50 canine samples and 22 UFH spiked samples for PT and 50 canine samples and 24 UFH spiked samples for APTT were used for the comparison study on the InCoag instruments and the Sysmex® CA-1500. Linear regression and calculation of correlation coefficient (R) were evaluated to assess the overall agreement of PT and APTT times between the InCoag and the Sysmex® CA-1500. Correlation of PT values demonstrate an R of 0.932 and for APTT an R of 0.937. These R values demonstrate strong correlation between the InCoag and Sysmex® CA-1500 reference analyzer across the ranges of canine PT and APTT values.

TEST	n	Sample Value Distribution		Correlation Equation	R
		low (sec)	high (sec)		
PT	72	17.40	35.70	y = 0.3787x + 15.438	0.9371
APTT	74	8.10	58.0	y = 0.8624x + 3.3746	0.9315

Displayed below are the correlation graphs for canine PT results using the InCoag versus the Sysmex® CA-1500 (Figure N).



Displayed below are the correlation graphs for canine APTT results using the InCoag versus the Sysmex® CA-1500 (Figure N).



Feline Method Comparison[9]

Materials & Methods

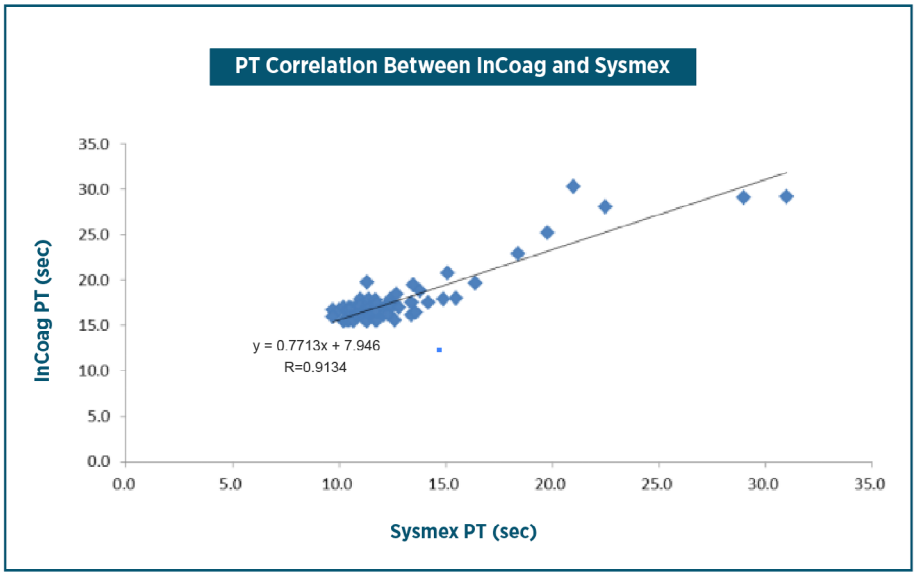
A total of 60 CWB samples were obtained from client owned cats of 9 different breeds. Samples were collected from cats with and without coagulopathies. Clinical samples were transferred into the manufacturer validated citrated tubes after venipuncture with a 3 mL syringe and butterfly catheter. An additional 11 samples were spiked with unfractionated heparin (UFH) in varying amounts to mimic abnormal coagulation times.
Each CWB sample was run on 2 InCoag analyzers simultaneously, obtaining values for PT and APTT. Each sample was then centrifuged to yield citrated plasma and then run on 1 Sysmex® CA-1500 coagulation reference analyzer to generate PT and APTT values for method comparison.

Results

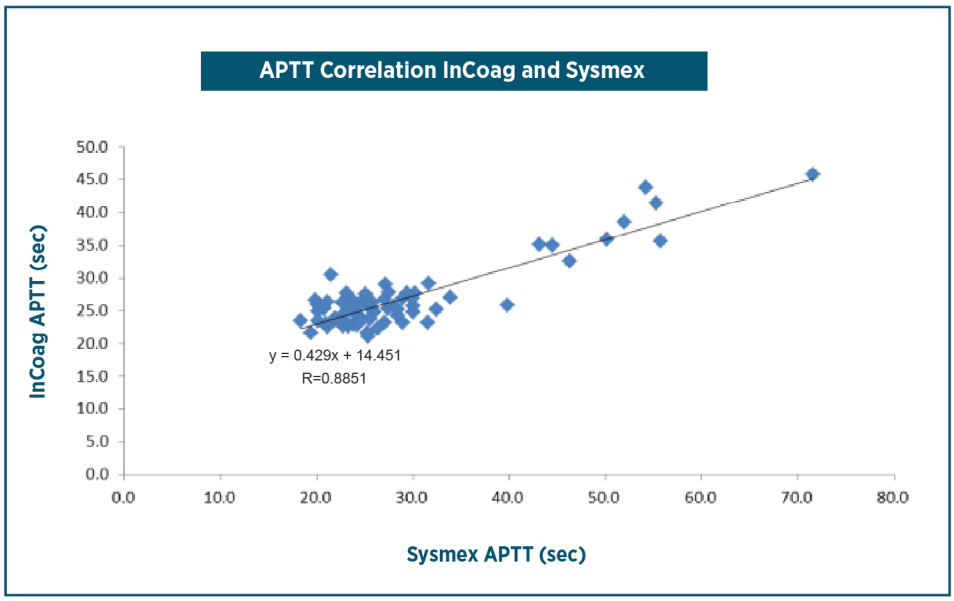
The results from 60 feline samples and 11 UFH spiked samples for PT and 59 feline samples and 11 UFH spiked samples for APTT were used for the comparison study on the InCoag and the Sysmex® CA-1500. Linear regression and calculation of correlation coefficient (R) were evaluated to assess the overall agreement of PT and APTT times between the InCoag and the Sysmex® CA-1500. Correlation for PT and APTT values were 0.885 and 0.913 respectively. These R values demonstrate strong correlation across the range of feline PT and APTT values between the InCoag and Sysmex® CA-1500 reference analyzer.

TEST	n	Sample Value Distribution		Correlation Equation	R
		low (sec)	high (sec)		
PT	71	15.5	30.3	y = 0.7713x + 7.946	0.9134
APTT	70	21.2	45.8	y=0.429x + 14.451	0.8851

Displayed below are the correlation graphs for feline PT results using the InCoag versus the Sysmex® CA-1500 (Figure N).



Displayed below are the correlation graphs for feline APTT results using the InCoag versus the Sysmex® CA-1500 (Figure N).



Summary

These studies demonstrate that InCoag is a precise and accurate point-of-care analyzer for the evaluation of the secondary system of blood coagulation in dogs and cats.

References

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