

Comparison of POC ACT Test Systems in Different Clinical Settings in a Large Academic Medical Center

Nichole Korpi-Steiner, PhD, DABCC, FACB
University of North Carolina

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UMass Memorial Medical Center

Worcester, MA

Vascular Surgery

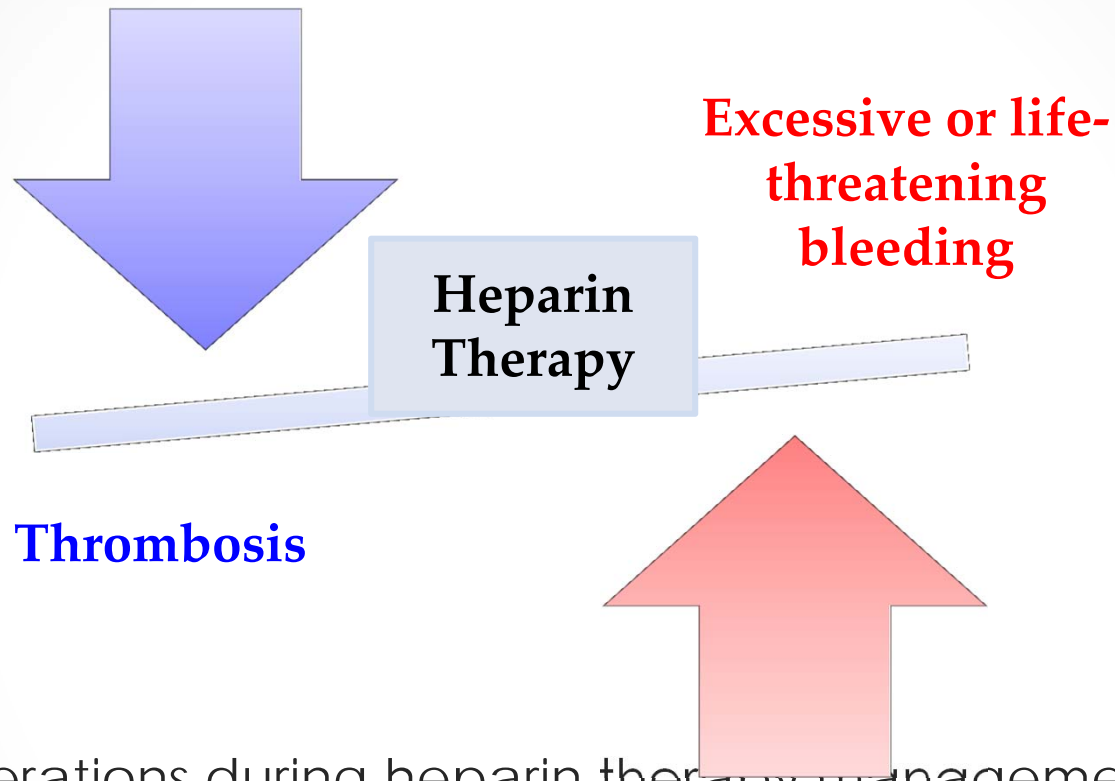
**Cardiac
Catheterization**



**Interventional
Radiology**

Cardiac Surgery

Heparin Therapy in Clinical Practice



- Considerations during heparin therapy management include:
 - Manufacturer/lot heparin activity
 - Patient sensitivity to heparin
 - Target patient coagulation status
 - Activated clotting time (ACT) measurement test system

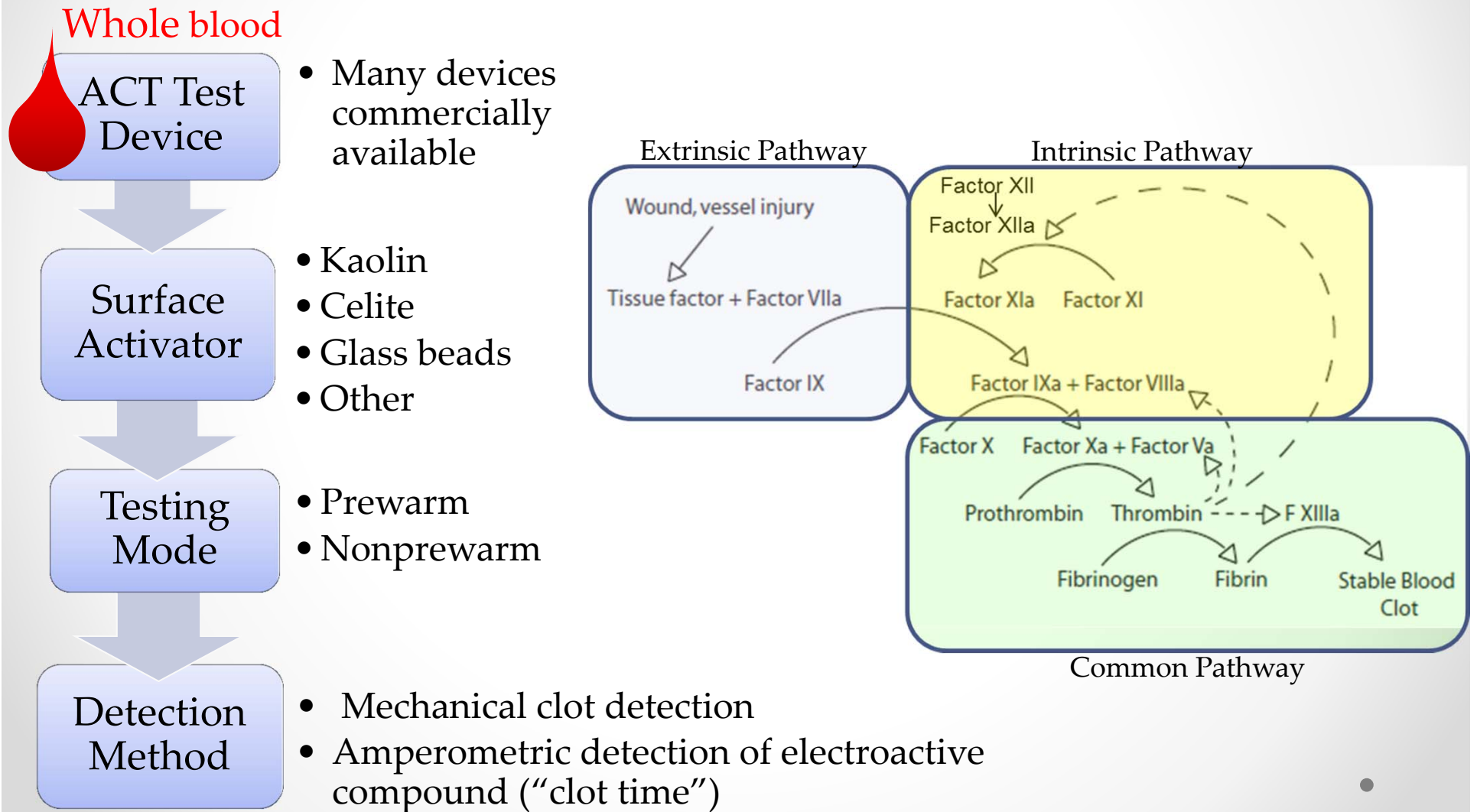
Activated Clotting Time (ACT)

- Functional assay used to monitor heparin inhibitory effect
- Measures the time required for activation of the intrinsic and common pathways of the coagulation cascade
- Numerous point of care ACT testing devices available, including but not limited to:



Activated Clotting Time (ACT)

- No gold standard ACT measurement test system exists and results may not be interchangeable between test systems



UMass Memorial Medical Center

ACT Test Systems



Vascular Surgery

ISTAT Prewarm Celite

**New POCT request:
ACTPlus Prewarm Kaolin**

Cardiac Catheterization

ISTAT Nonprewarm Celite



Interventional Radiology

ISTAT Prewarm Celite

Cardiac Surgery

HMSPlus Prewarm Kaolin

Study Design

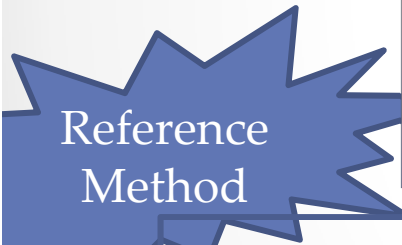
Sample Selection:
41 Venous Whole Blood Samples

17 Cardiac Catheterization Patients (17 WB samples)

5 Cardiopulmonary Bypass Patients (20 WB samples)

2 Vascular Surgery Patients (4 WB samples)

ACT Measurement Test Systems
Duplicate measurements per test system (n=410)



HMS Plus
Prewarm
Kaolin
Mechanical

ISTAT
Prewarm
Celite
Amperometric

ISTAT
NonPrewarm
Celite
Amperometric

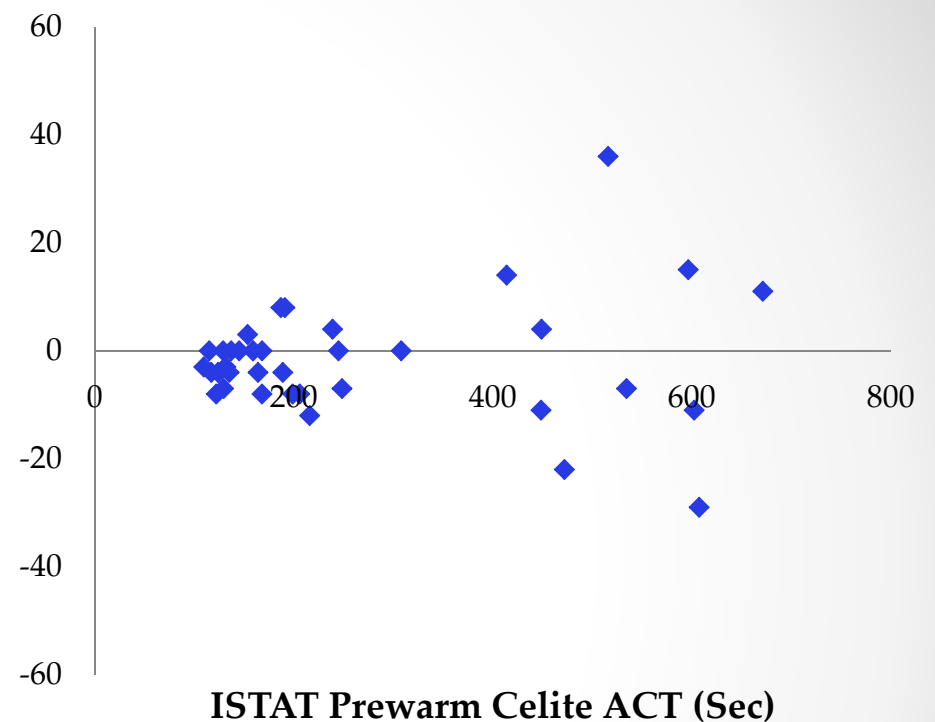
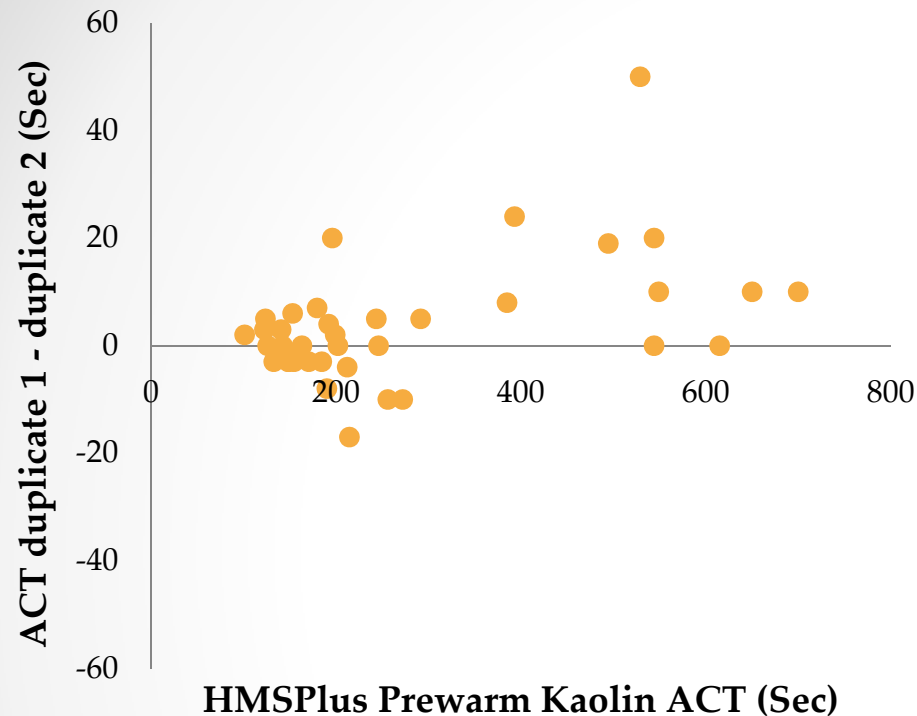
ACT Plus
Prewarm
Kaolin
Mechanical

ISTAT
Prewarm
Kaolin
Amperometric

Systems In-Use

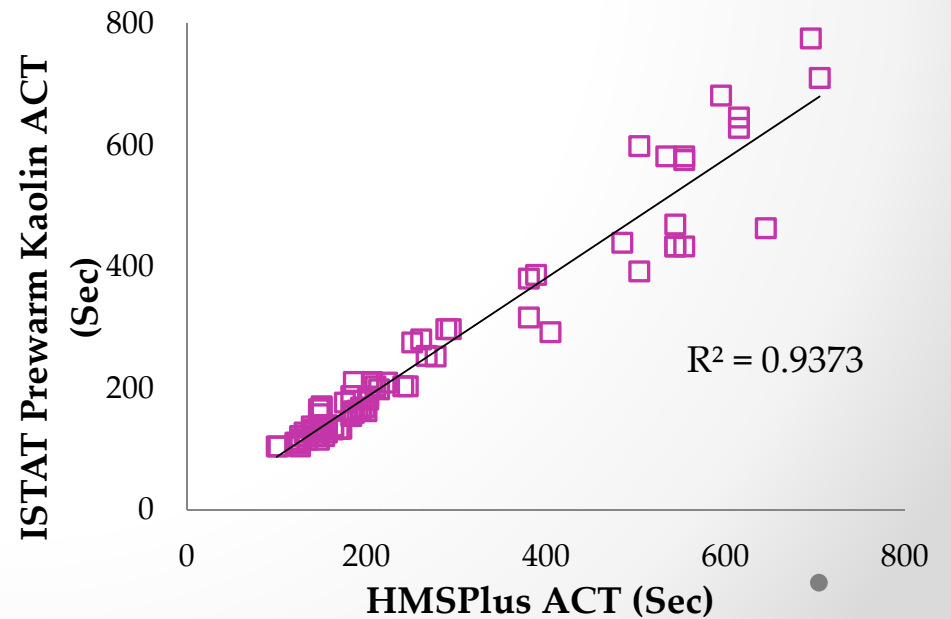
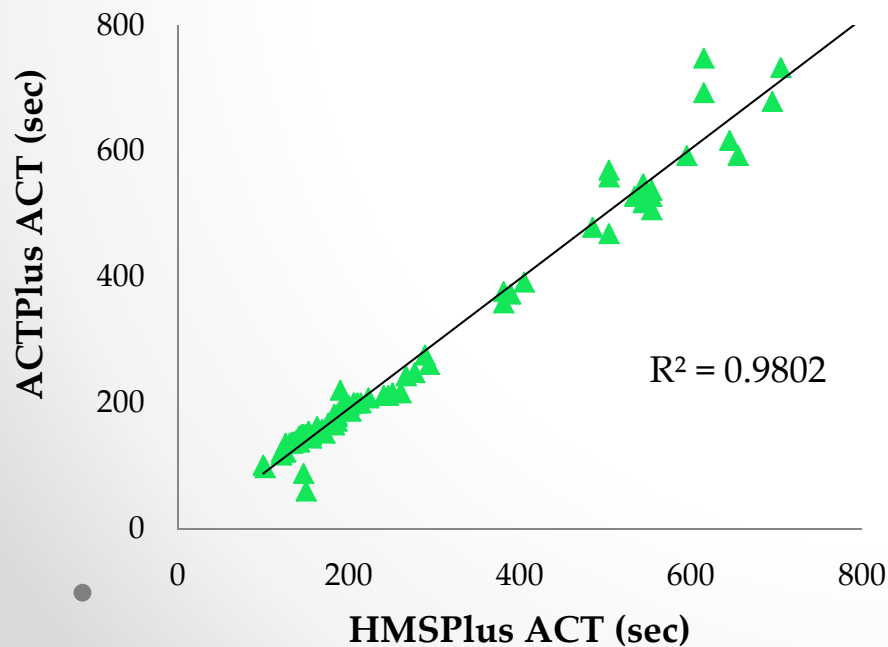
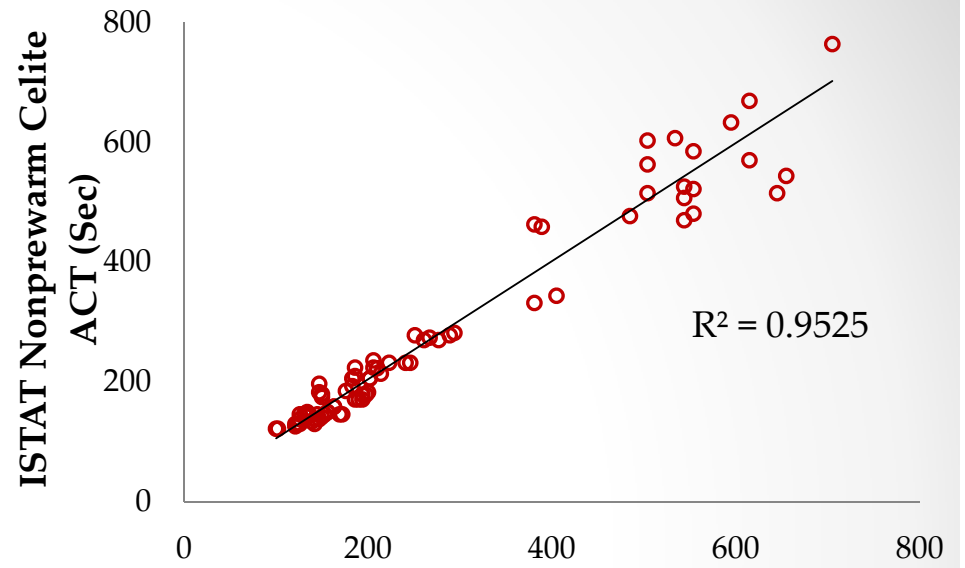
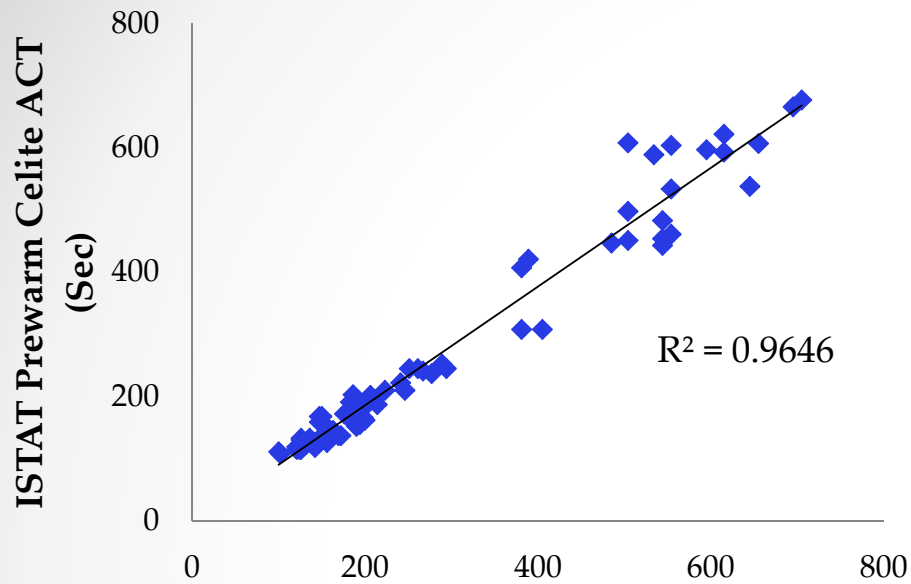
Test Systems

ACT: Test System Reproducibility

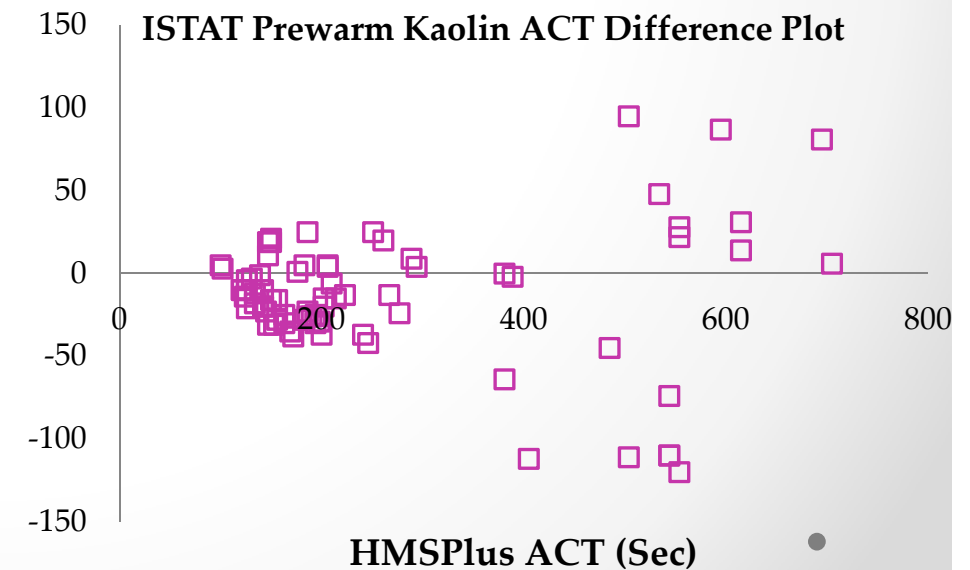
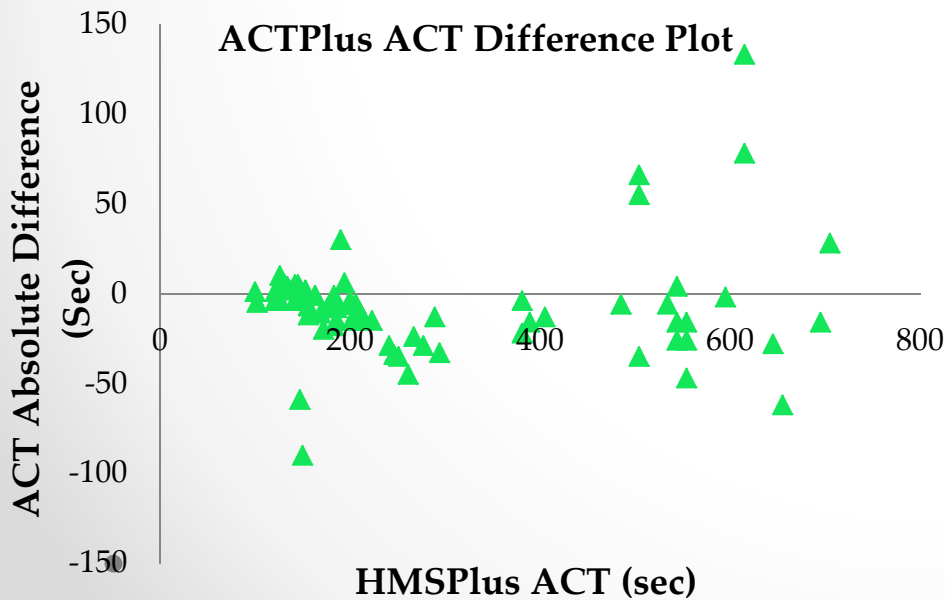
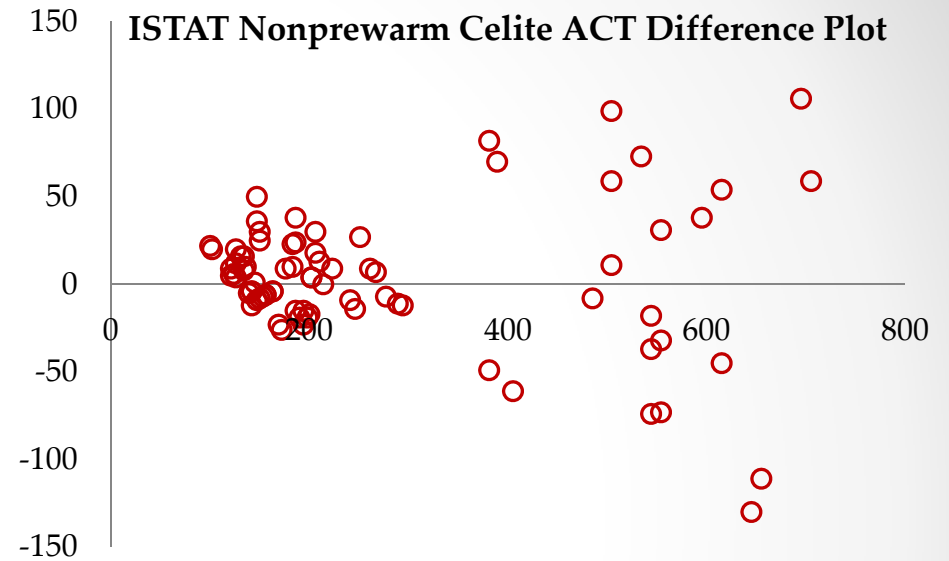
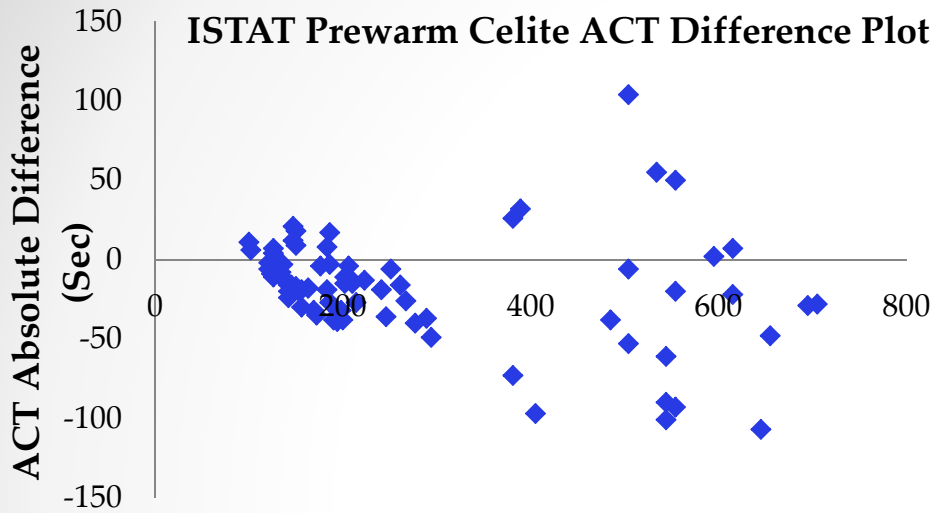


Device	Mode	Activator	Method Duplicate 1 - Duplicate 2 ACT	
			Mean (\pm SD; sec)	
			100-299 sec	≥ 300 sec
HMSPlus	Prewarm	Kaolin	-0.3 (± 6.6)	20 (± 26)
iSTAT	Prewarm	Celite	-2.4 (± 4.7)	5.8 (± 27)
iSTAT	Non-prewarm	Celite	3.5 (± 5.1)	-13 (± 44)
ACTPlus	Prewarm	Kaolin	1.4 (± 9.9)	2.1 (± 37)
iSTAT	Prewarm	Kaolin	0.2 (± 6.8)	-26 (± 22)

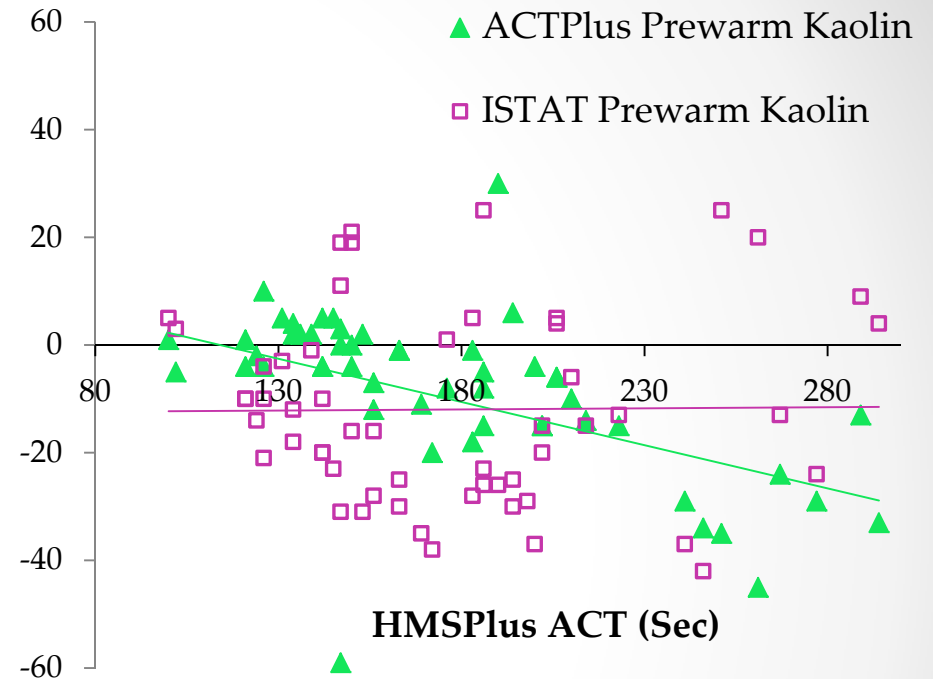
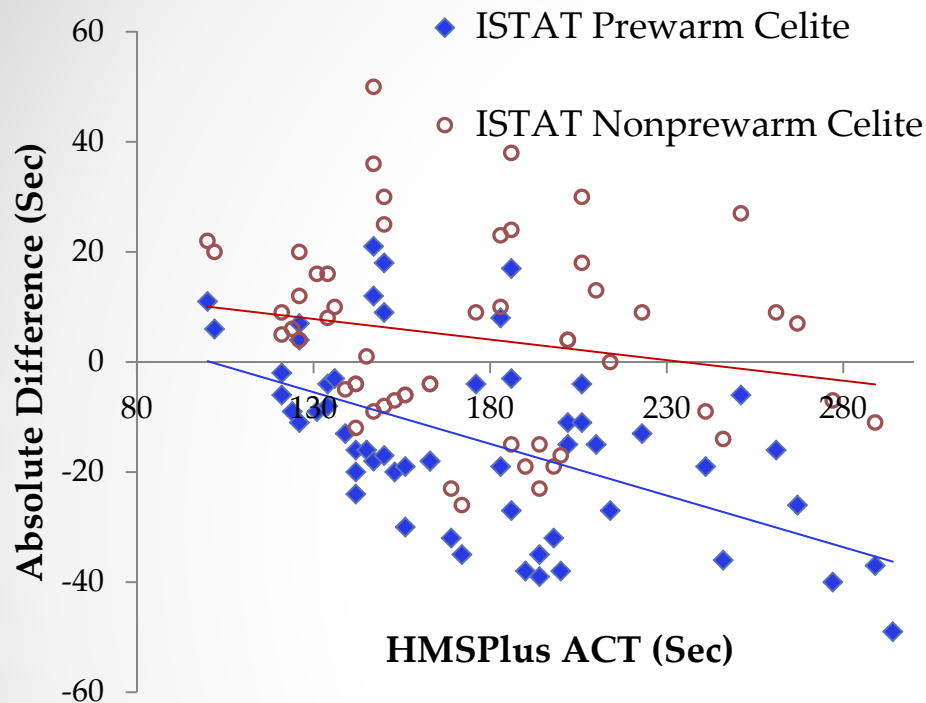
ACT: Linear Regression Analyses



ACT: Bland Altman Analyses

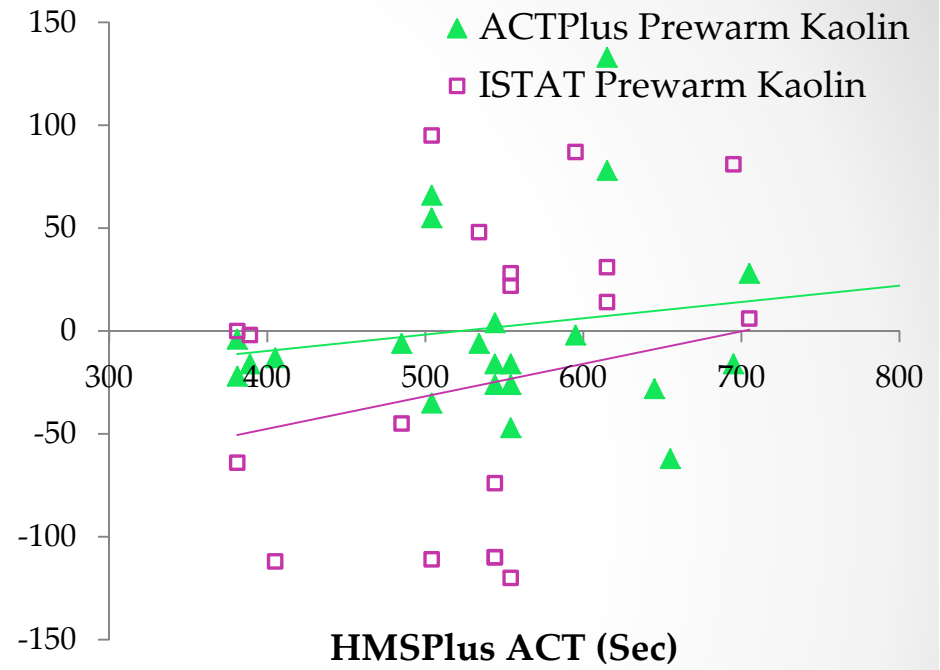
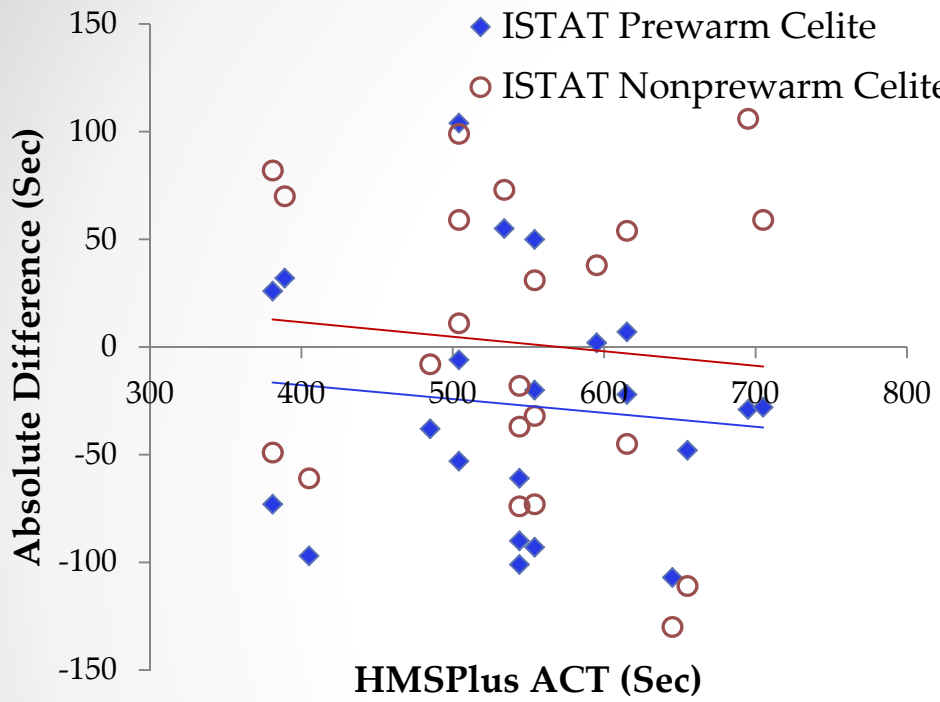


Moderate Range ACT: Bland Altman Analyses



Device	Mode	Activator	Test Method - HMSPlus	
			ACT Mean (\pm SD)	Difference (sec)
			100-299 sec	
iSTAT	Prewarm	Celite	-14 (\pm 16)	
iSTAT	Non-prewarm	Celite	4.2 (\pm 17)	
ACTPlus	Prewarm	Kaolin	-10 (\pm 19)	
iSTAT	Prewarm	Kaolin	-12 (\pm 18)	

High Range ACT: Bland Altman Analyses



Device	Mode	Activator	Test Method - HMSPlus	
			ACT Mean (\pm SD)	Difference (sec)
iSTAT	Prewarm	Celite	-27 (\pm 57)	≥ 300 sec
iSTAT	Non-prewarm	Celite	2.0 (\pm 69)	
ACTPlus	Prewarm	Kaolin	3.5 (\pm 45)	
iSTAT	Prewarm	Kaolin	-26 (\pm 80)	

UMass ACT Testing Practices: Win-Win!

Vascular Surgery

HMSPlus Prewarm Kaolin

Cardiac Catheterization

ISTAT Nonprewarm Celite



Interventional Radiology

ISTAT Nonprewarm Celite

Cardiac Surgery

HMSPlus Prewarm Kaolin

Summary / Conclusions

- Many variables to consider with ACT test systems
 - Testing device
 - Surface activator type
 - Test calibration mode
 - Detection method
- No gold standard ACT test system exists
- Comparison studies that span the ACT range used in clinical practice are needed when considering a change in ACT test system
- The optimal ACT measurement test system depends on the analytical performance characteristics for a given ACT target range and clinical concordance of ACT values

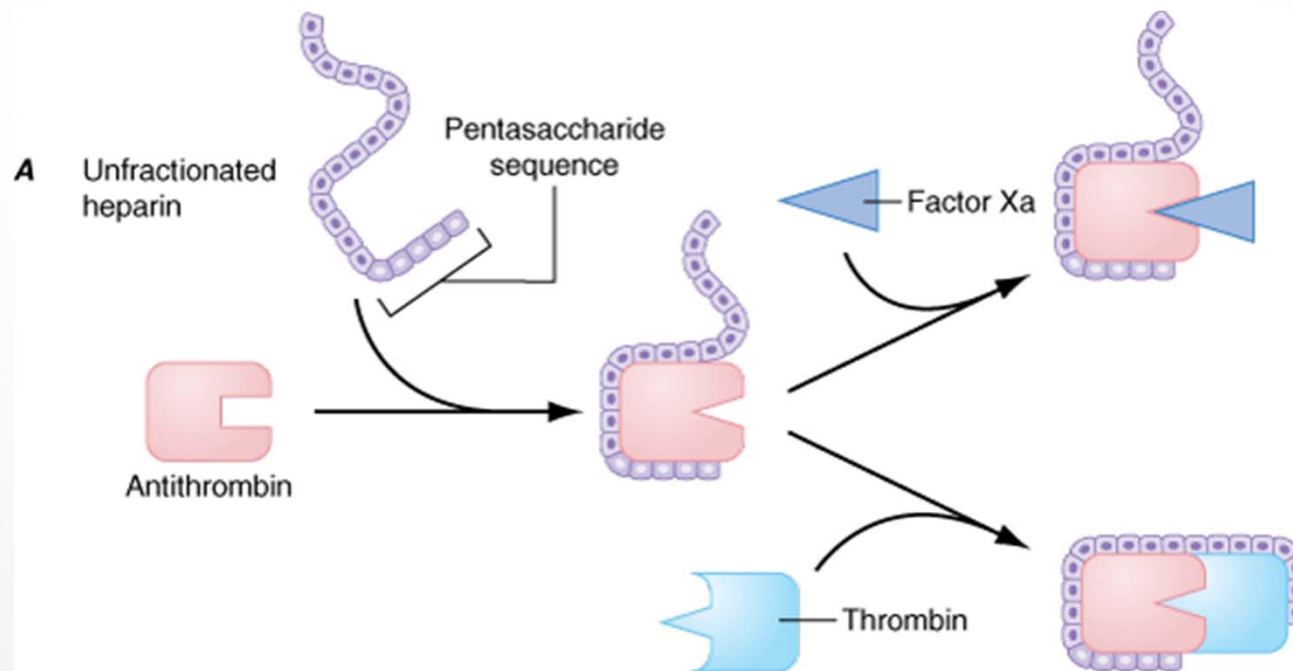


Acknowledgements

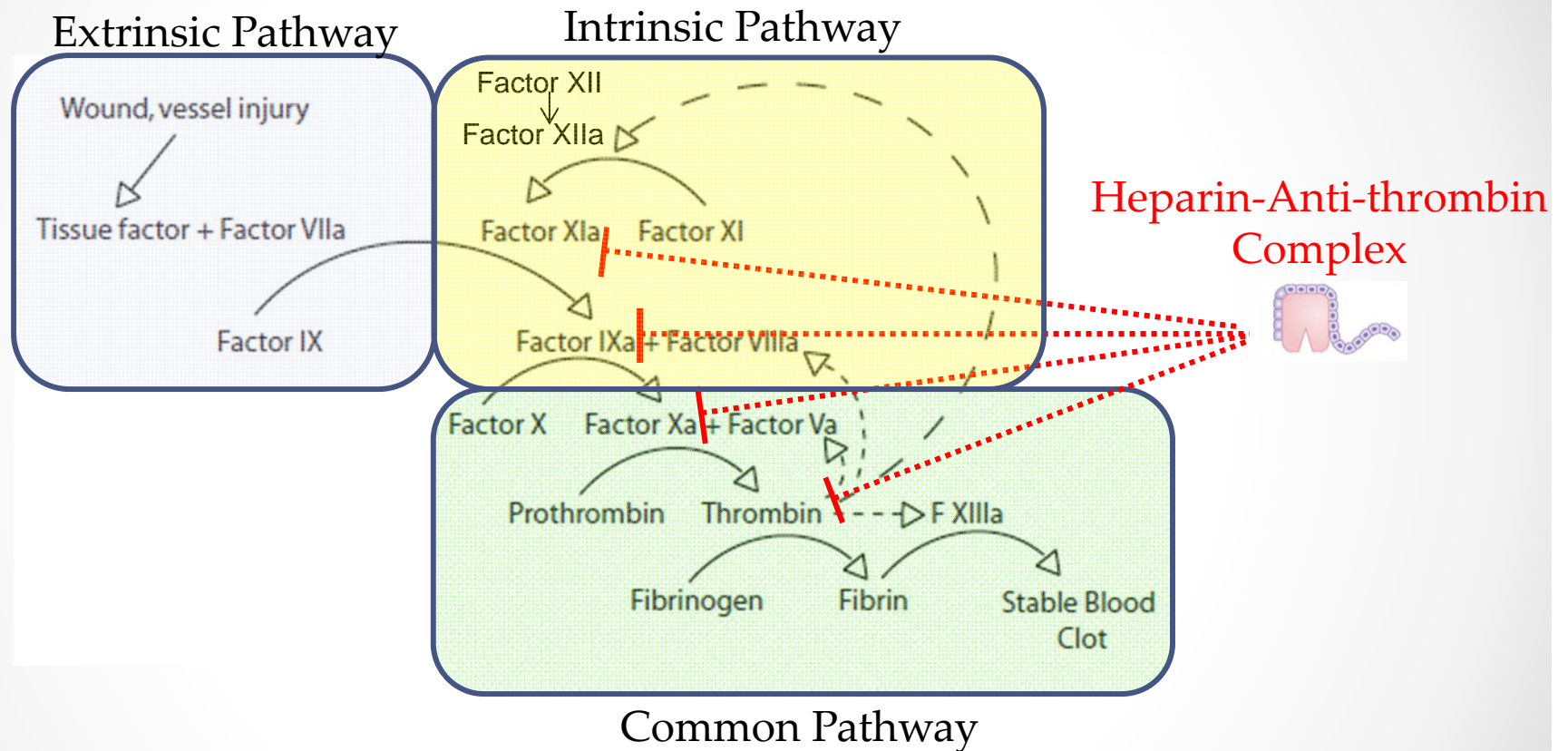
- UMMMC Multi-disciplinary Team
 - C. Felice Jakubiak
 - Patti Reichle
 - Mark Wante
 - Joan Stairs
 - J. Matthias Walz
 - Andrew Schanzer
 - L.V. Rao

Heparin Therapy

- Anti-coagulation therapy to prevent thrombosis
- Heparin indirectly inhibits factors IIa (thrombin) and Xa through binding and potentiating anti-thrombin activity



Heparin Effect on the Coagulation Cascade



- Heparin-anti-thrombin complex inhibits coagulation factors in the intrinsic and common pathways to suppress clot formation