iSTAT: The Halifax Perfusion Experience

Abbott

INTRODUCING OUR
EASIEST DEVICE YET

Diagnostic testing, and everything that goes with it, isn't always easy.

But the NEW i-STAT Alinity system can make it easier.

i-STAT Alinity

With-Patient Testing
Revolutionized

CHOOSE TRANSFORMATION™

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Dalhousie University

AGENDA

i-STAT in the Halifax CVOR

- How it all started:
  - ACT Monitoring
    - Previous Analyzer QA
    - Comparative Study & the Gold standard
  - ABGs in the Halifax CVOR
    - CG4 and CG8 vs current analyzer

INTRODUCTION:

ACTIVATED CLOTTING TIME

- Time required for whole blood to clot following activation of intrinsic coagulation cascade
- *Required* for CPB
- ***No*** internationally accepted '*gold standard*' and no '*true*' ACT value
- Most ACT analyzers use mechanical methods to detect clot formation
  - i-STAT does not….

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HOW IT ALL STARTED

QUALITY ASSURANCE INITIATIVE: ORIGINAL ACT MONITORING

- Original ACT analyzer
  - Helena Actalyke XL®
    - Requires 0.5 ml per test
  - Stops at 1500 seconds
- Concerns with this ACT analyzer
  - Quality controls
  - Large potential for user-error
    - Volume-dependent/reagent on sides of tube/improper mixing
  - Volume of blood required
    - Pediatric patients on ECLS

QUALITY ASSURANCE INITIATIVE: *THE QUESTION*

- How reliable/How much variation between chambers?

HOW IT ALL STARTED

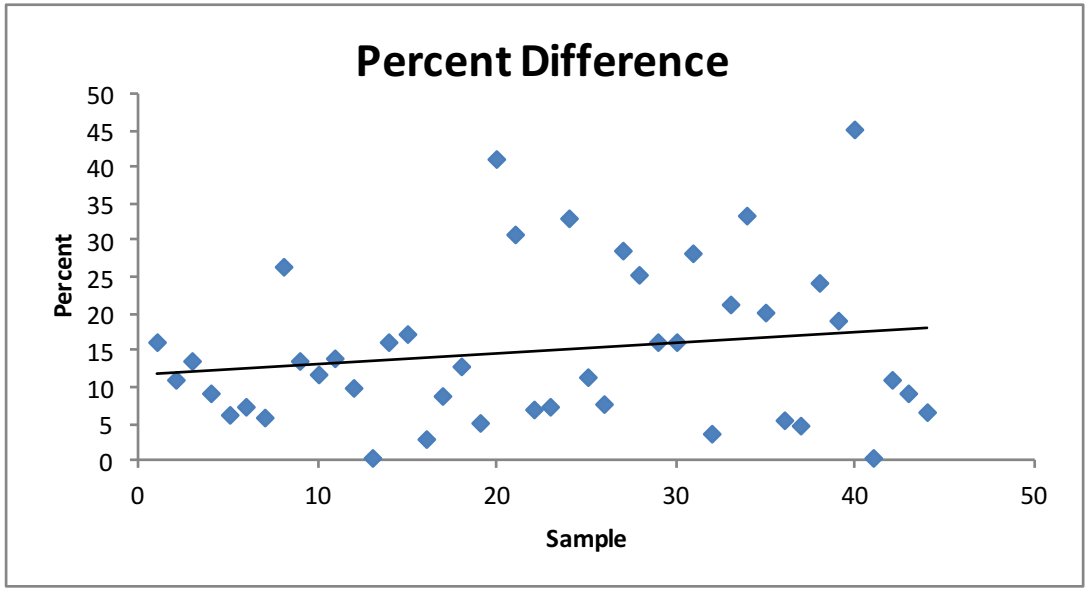
METHODOLOGY:

- Multiple dual-chamber machines
- *Minimize Human error:*
  - *Only* three users
  - *1 ml* syringes (standard of practice: 3 ml syringe)
  - n = 44
  - Two tubes per test, compare ACT values

QA INITIATIVE: CONSISTENCY OF ORIGINAL ACT ANALYZER

Percent Difference between wells:

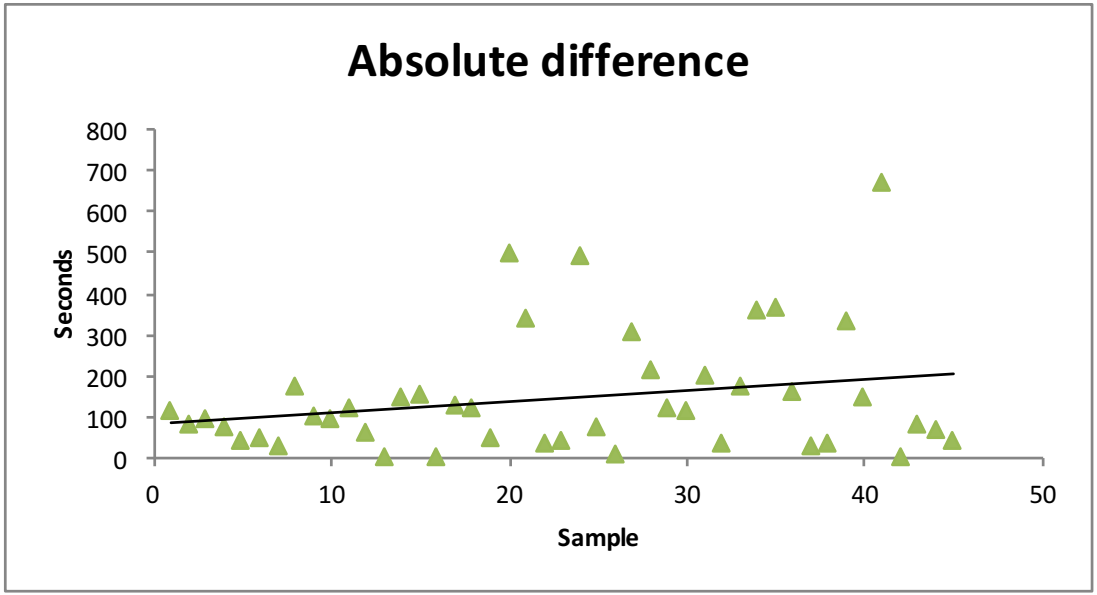
- Mean: 14.4 ± 9.7 %
  - Range: **0– 45 % difference**



QA INITIATIVE: CONSISTENCY OF ORIGINAL ACT ANALYZER

Absolute Difference between wells:

- Mean: 129 ± 123 seconds
  - Range: **0– 667** second difference



CONCLUSION:

Based on the apparent lack of consistency between channels, there is *clearly* concern for its use in clinical decision making….

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I-STAT:

ACT DETECTION:

- Kaolin-activated clotting time test
- While other systems use mechanical methods, i-STAT uses a direct assessment
- Electrochemical sensor to amperometrically detect conversion of the thrombin substrate with amide linkage mimicking fibrinogen
- Amperometry:
  - Detection of electroactive compounds
- Thrombin + substrate:
  - Produces electroactive compound
- Affected less by environmental factors, such as temperature and fibrinogen (Lewandrowski *et al* and Schussler *et al.*)

HOW DOES I-STAT COMPARE TO OTHER ACT ANALYZERS?

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USING THE I-STAT:

Step 1: Scan cassette bar code, insert 2-3 drops into cartridge

Step 3: View the results on the handheld screen within minutes

Step 2: Close cartridge and insert into the i-STAT handheld

Step 4: Upload information automatically into the LIS/HIS

https://www.pointofcare.abbott/int/en/offerings/istat/istat-handheld

I-STAT SYSTEM COMPARATIVE VERIFICATION STUDY IN TWO CANADIAN HOSPITALS

UNIVERSITY OF ALBERTA

- *Hemochron Signature Elite*
- Duplicate analysis
- 48 tests

FOOTHILLS MEDICAL CENTRE

- *Medtronic ACT Plus*
- Duplicate analysis
- 59 tests

UNIVERSITY OF ALBERTA

i-STAT vs *Hemochron Signature Elite*

Table 1 below compares the approximate imprecisions of the *i-STAT System* and *Hemochron Signature Elite* for the 3 ranges. The coefficient of variation (CV) for the *i-STAT System* was less than 6% for the entire range, giving clinicians the confidence in the interpretation of results. In comparison, *Hemochron Signature Elite* exhibited a larger CV, which may cause misinterpretation of the heparin status, especially at higher ACT values.

Table 1

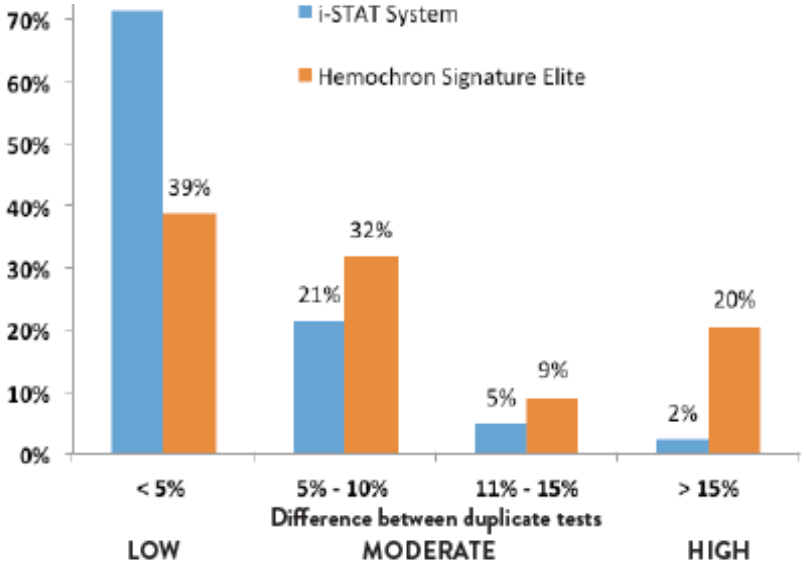
	i-STAT SYSTEM			HEMOCHRON SIGNATURE ELITE		
ACT Range (s)	Mean (s)	SD (s)	CV (%)	Mean (s)	SD (s)	CV (%)
90 - <400	114	3.5	3.1	113	5.7	5.1
400 - 600	464	17.5	3.8	553	51	9.2
>600	728	41.1	5.6	761	154	20.3

UNIVERSITY OF ALBERTA

i-STAT vs *Hemochron Signature Elite*

Imprecision analysis

Figure 1 below demonstrates the high precision of the *i-STAT System* with 71% of the duplicate samples varying less than 5% from each other. In comparison, *Hemochron Signature Elite* samples had more divergent duplicates with a fifth of the samples exceeding 15%.



FOOTHILLS MEDICAL CENTRE

i-STAT vs *Medtronic ACT Plus*

The *i-STAT System* and *Medtronic ACT Plus* reported comparable variation and distribution.

Of note, the *i-STAT System* duplicate testing was performed using two separate analyzers whereas the *Medtronic ACT Plus* results were from a single analyzer, running each test sample twice for duplicate results.

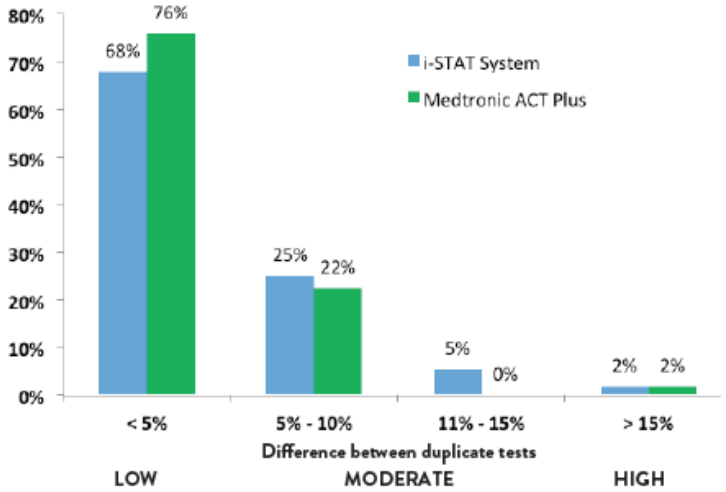
Table 2

	i-STAT SYSTEM			MEDTRONIC ACT PLUS		
ACT Range (s)	**Mean (s)**	**SD (s)**	**CV (%)**	**Mean (s)**	**SD (s)**	**CV (%)**
90 - <400	114.3	0	0	172.9	8.5	4.9
400 - 600	458	16.9	3.7	503	14.6	2.9
>600	729.1	28.2	3.9	694	38.9	5.6

FOOTHILLS MEDICAL CENTRE

i-STAT vs *Medtronic ACT Plus*
Imprecision Analysis

FIGURE 4: IMPRECISION ANALYSIS OF i-STAT SYSTEM AND MEDTRONIC ACT PLUS



i-STAT ACT offers precision and reliability

i-STAT also offers many other clinical tests…

Patient testing revolutionalized…

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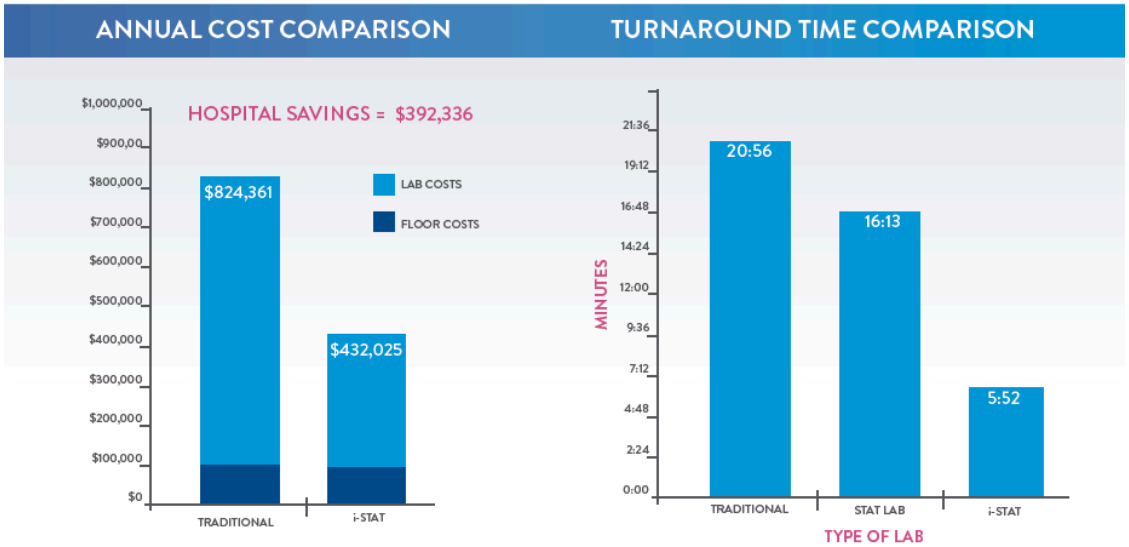
i-STAT ABG

LABORATORY PROCESS IMPROVEMENT THROUGH POINT-OF-CARE TESTING

White paper from Methodist Clinical Laboratory Services of Indianapolis



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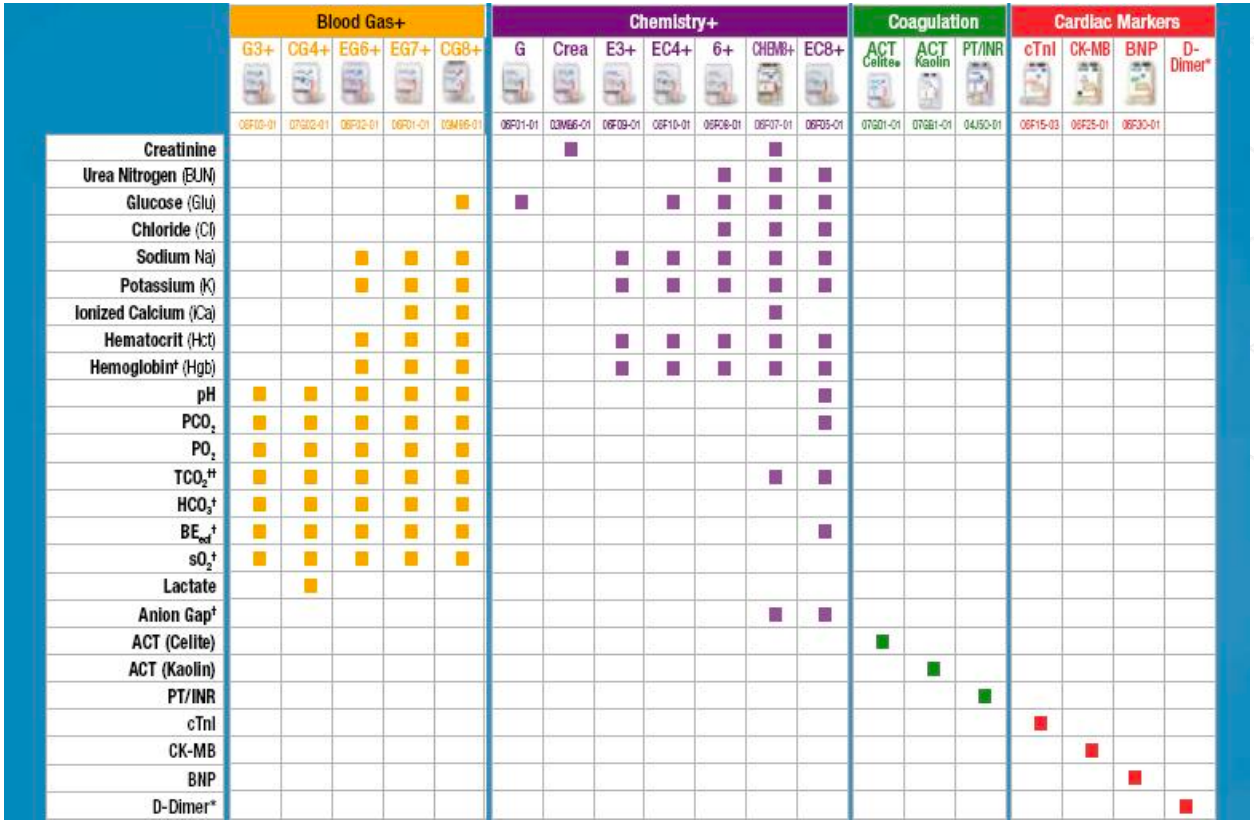
I-STAT CARTRIDGES: VERSATILITY…



	Blood Gas+					Chemistry+							Coagulation			Cardiac Markers			
	G3+	CG4+	EG6+	EG7+	CG8+	G	Crea	E3+	EC4+	6+	CHEM8+	EC8+	ACT Celite	ACT Kaolin	PT/INR	cTnI	CK-MB	BNP	D-Dimer*
	06F02-01	07G02-01	06F32-01	06F01-01	03M86-01	06F01-01	03M66-01	06F09-01	06F10-01	06F06-01	06F07-01	06F05-01	07G01-01	07GE1-01	04J50-01	06F15-03	06F25-01	06F30-01	
Creatinine							■				■								
Urea Nitrogen (BUN)										■	■	■							
Glucose (Glu)					■	■			■	■	■	■							
Chloride (Cl)										■	■	■							
Sodium Na)			■	■	■			■	■	■	■	■							
Potassium (K)			■	■	■			■	■	■	■	■							
Ionized Calcium (iCa)				■	■						■								
Hematocrit (Hct)			■	■	■			■	■	■	■	■							
Hemoglobin† (Hgb)			■	■	■			■	■	■	■	■							
pH	■	■	■	■	■							■							
PCO_2	■	■	■	■	■							■							
PO_2	■	■	■	■	■														
TCO_2††	■	■	■	■	■						■	■							
HCO_3†	■	■	■	■	■														
BE_{ecf}†	■	■	■	■	■							■							
sO_2†	■	■	■	■	■														
Lactate		■																	
Anion Gap†											■	■							
ACT (Celite)													■						
ACT (Kaolin)														■					
PT/INR															■				
cTnI																■			
CK-MB																	■		
BNP																		■	
D-Dimer*																			■

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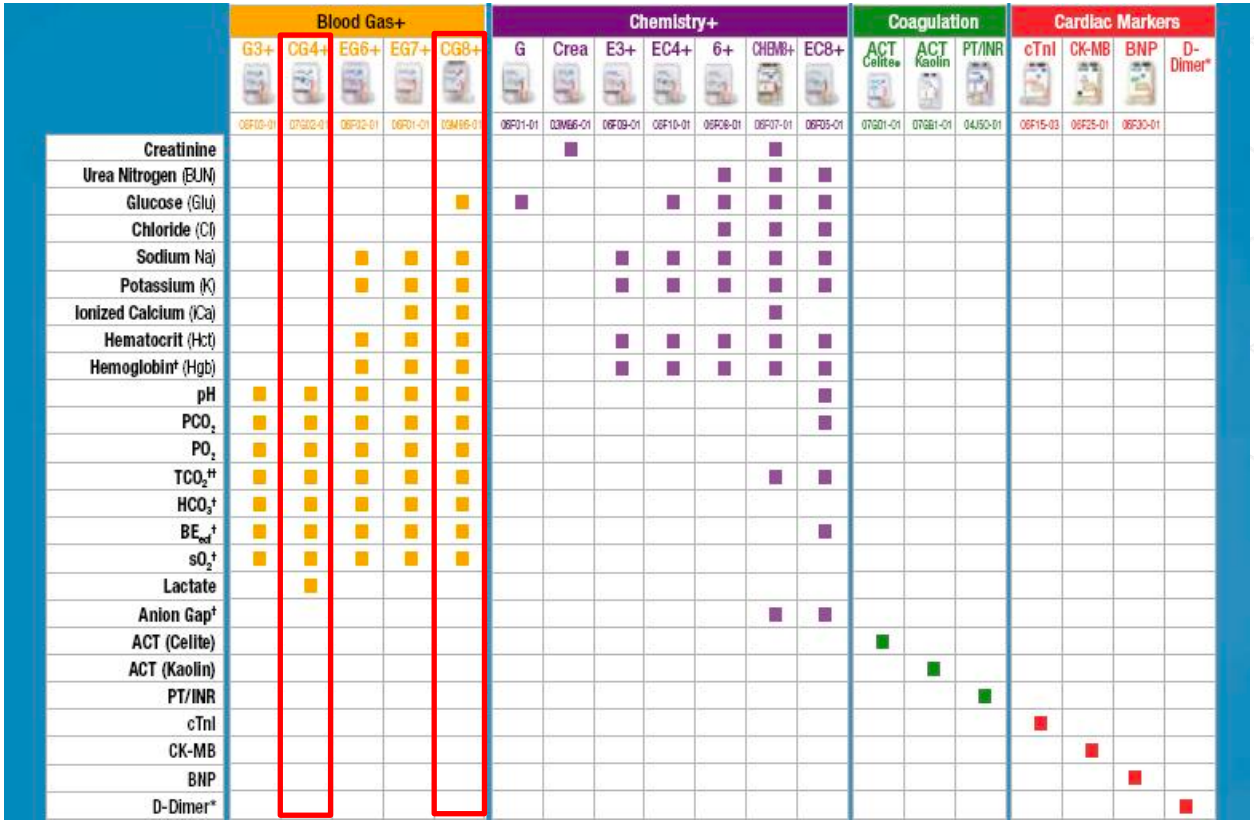
I-STAT CARTRIDGES: VERSATILITY…



	Blood Gas+					Chemistry+							Coagulation			Cardiac Markers			
	G3+	CG4+	EG6+	EG7+	CG8+	G	Crea	E3+	EC4+	6+	CHEM8+	EC8+	ACT Celite	ACT Kaolin	PT/INR	cTnI	CK-MB	BNP	D-Dimer*
	06F02-01	07G02-01	06F32-01	06F01-01	09M86-01	06F01-01	02M66-01	06F09-01	06F10-01	06F06-01	06F07-01	06F05-01	07G01-01	07GE1-01	04J50-01	06F15-03	06F25-01	06F30-01	
Creatinine							■				■								
Urea Nitrogen (BUN)										■	■	■							
Glucose (Glu)					■	■			■	■	■	■							
Chloride (Cl)										■	■	■							
Sodium Na			■	■	■			■	■	■	■	■							
Potassium (K)			■	■	■			■	■	■	■	■							
Ionized Calcium (iCa)				■	■						■								
Hematocrit (Hct)			■	■	■			■	■	■	■	■							
Hemoglobin† (Hgb)			■	■	■			■	■	■	■	■							
pH	■	■	■	■	■							■							
PCO_2	■	■	■	■	■							■							
PO_2	■	■	■	■	■														
TCO_2††	■	■	■	■	■						■	■							
HCO_3†	■	■	■	■	■														
BE_{ecf}†	■	■	■	■	■							■							
sO_2†	■	■	■	■	■														
Lactate		■																	
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BNP																		■	
D-Dimer*																			■

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I-STAT ABG

CARTRIDGE-BASED ANALYSIS

- Patient sample:
  - *GEM4000* (standard of care)
  - *i-STAT CG4+*
  - *i-STAT CG8+*
- Comparisons:
  - *GEM4000* vs *CG4+*
  - *GEM4000* vs *CG8+*
  - *CG4+* vs *CG8+* (pH, gases and bicarbonate)
- Calculation:
  - % Difference

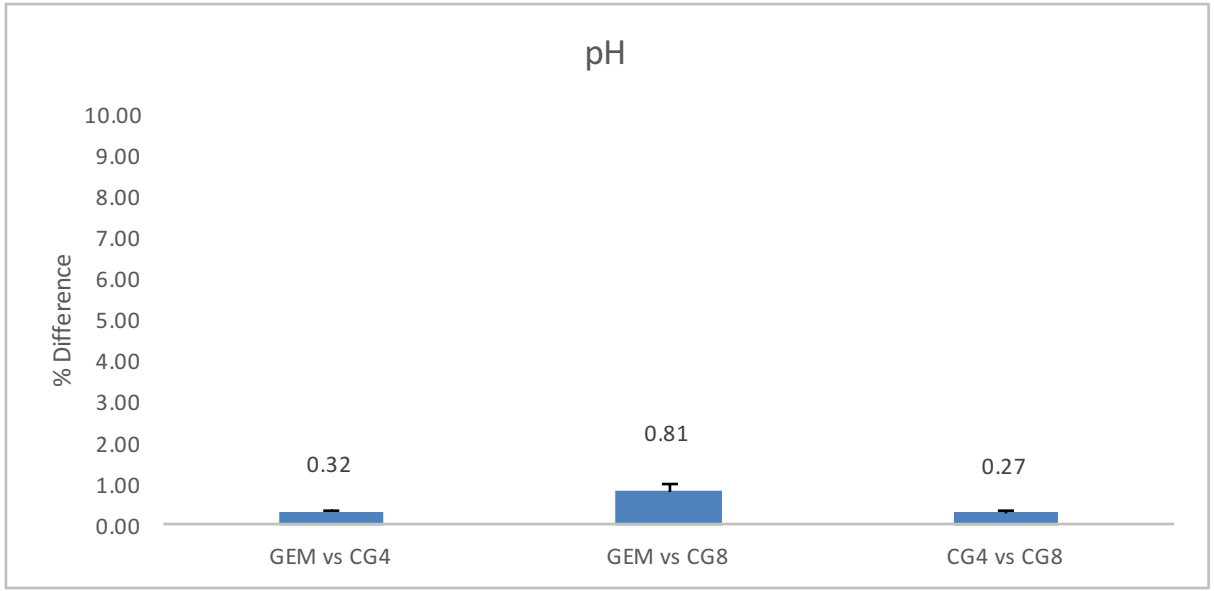
I-STAT ABG

CARTRIDGE-BASED ANALYSIS

- Detection System:
  - Measured potentiometrically using Nernst equation:
    - pH, pCO_2, Na, K, Ca, HCO_3, BE, anion gap
  - Measured amperiometrically:
    - pO_2, SO_2, lactate, glucose
  - Measured conductometrically:
    - Hct

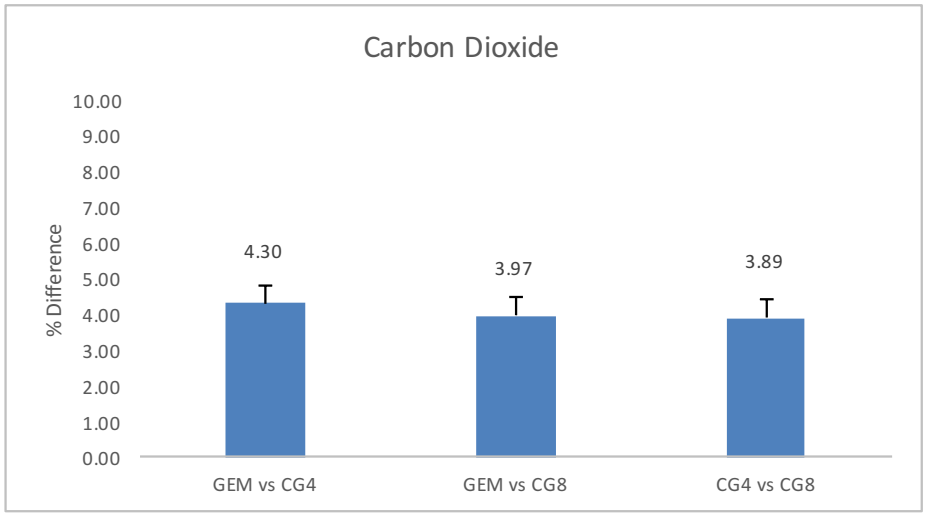
I-STAT VS GEM4000

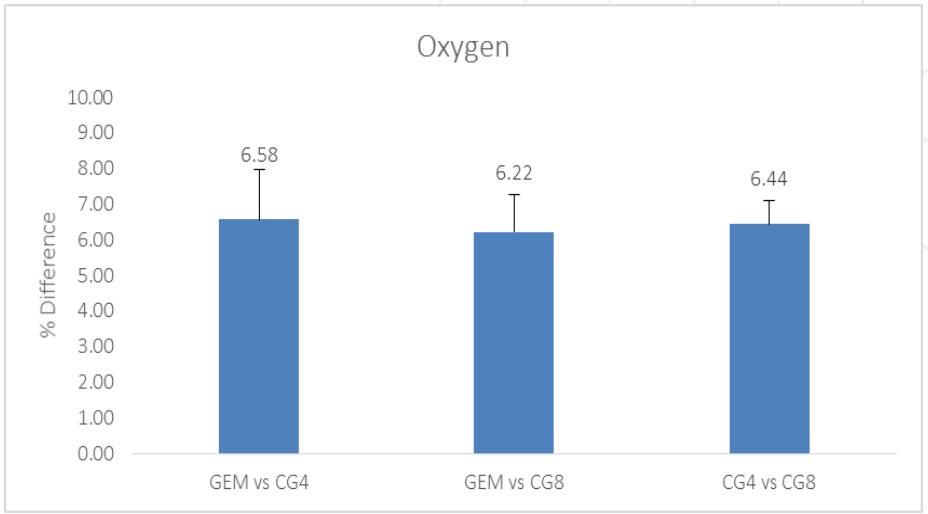
i-STAT vs GEM4000: pH



I-STAT VS GEM4000

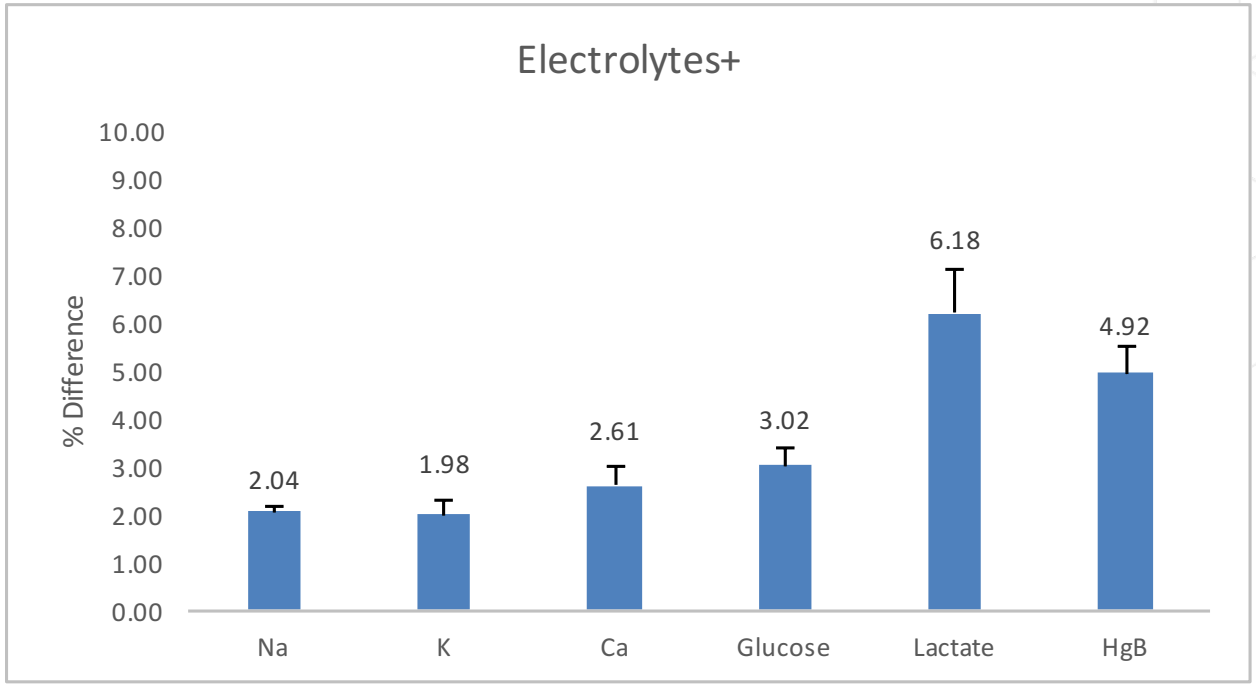
i-STAT vs GEM4000: pCO2 and pO2





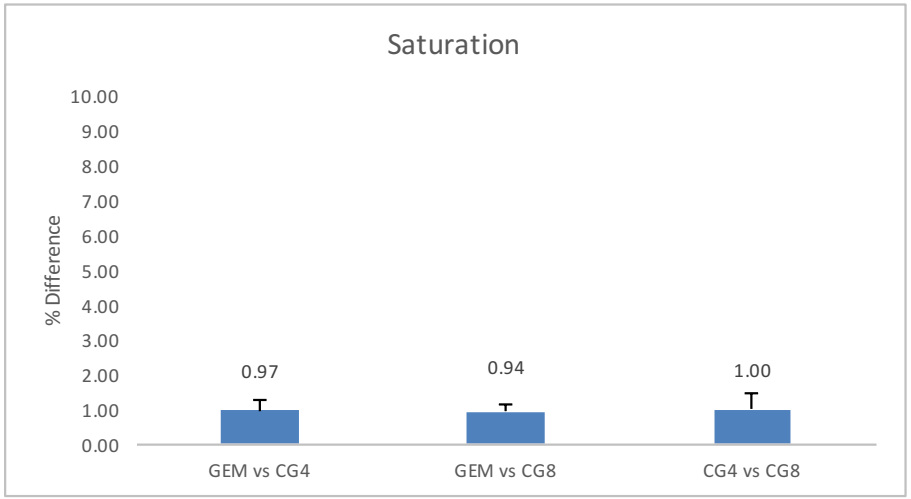
I-STAT VS GEM4000

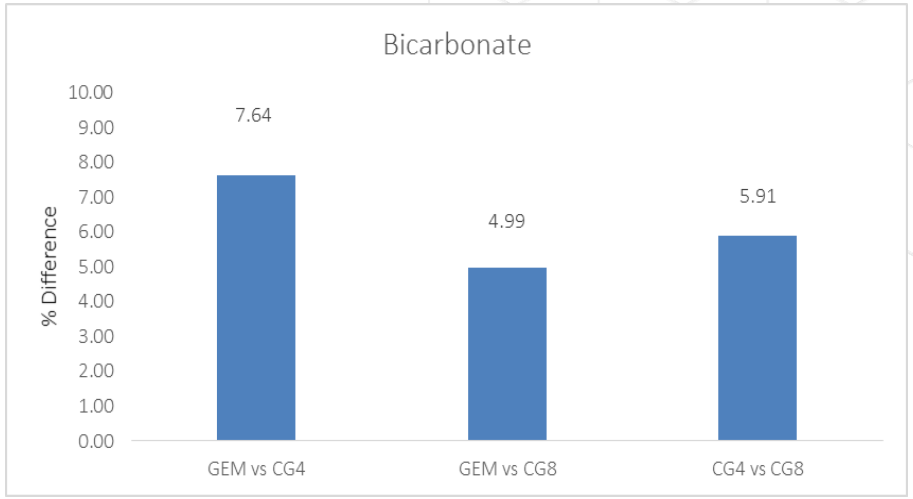
i-STAT vs GEM4000: Electrolytes and HgB



I-STAT VS GEM4000

Saturation and Bicarbonate





i-STAT CG4+ and CG8+ offer precision and reliability

i-STAT versatility beyond standard ABG testing…

I-STAT ACT AND ABG COMMENTS:

Pros

- Easy to use
- Small blood volume
- Reproducible/reliable
  - Reduction in '*human error*' (ACT)
  - Quality control
- Portable:
  - TAVI crash
  - IWK
- Reduced wastage:
  - GEM4000 wastage
  - ~100 tests in high volume OR
  - ~300-400 tests in low volume OR
- Long battery life

Cons

- Time requirement
  - QC conducted on each cassette
- Ability of surgeon to see the ACT time

Questions?


Abbott