

Evaluation of Lactate Methods

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Introduction

- **Lactate measurement is important in the care of critically ill adult and pediatric patients.**
- **Several methods exist for lactate measurement both at the point of care and in the central laboratory.**
- **Few studies have compared the performance of multiple point of care and laboratory based lactate assays.**

Introduction

- **Point of Care improves patient outcomes**
- **Follow up may be done with central lab assays**
- **Bias between methods may mislead clinicians on trends or prognosis**

Lactate Methods

- Radiometer ABL 725
- i-STAT CG4+
- Nova Biomedical Lactate Plus Meter (Investigational Use Only)
- Roche Integra 400 Plus
- Vitros 250 (Reference Method)

Outline

- **Method Validation**
 - **Method Comparison**
 - **Stability Studies**
 - **Linearity**
 - **Precision**
 - **Method Correlation**

Method Comparison

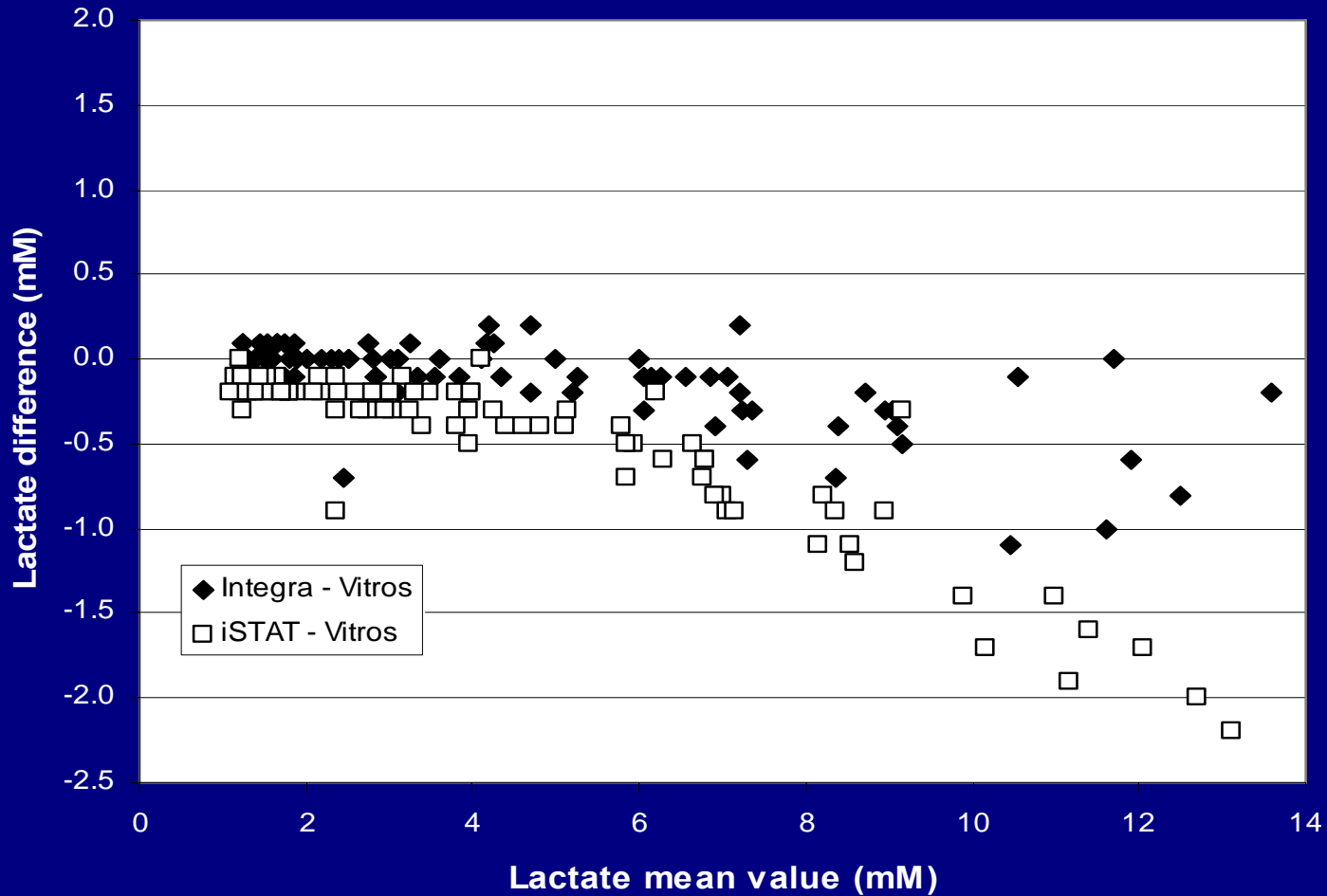
- 90 de-identified whole blood specimens (ED and ICU)
- Whole blood analysis on Radiometer ABL 725, i-STAT CG4+, and Nova Lactate Plus within 5 minutes
- Specimens were centrifuged immediately
- Plasma kept on ice and tested on Roche Integra 400 and Vitros 250 (within 1 hr of plasma separation)
- Vitros used as reference method

Method Comparison

Analyzer	Slope	Intercept	R²
Integra 400	0.95	0.106	0.9967
Radiometer ABL 725	0.87	0.135	0.9957
i-STAT CG4+	0.87	0.135	0.9957
Nova Lactate Meter	1.06	0.206	0.9866

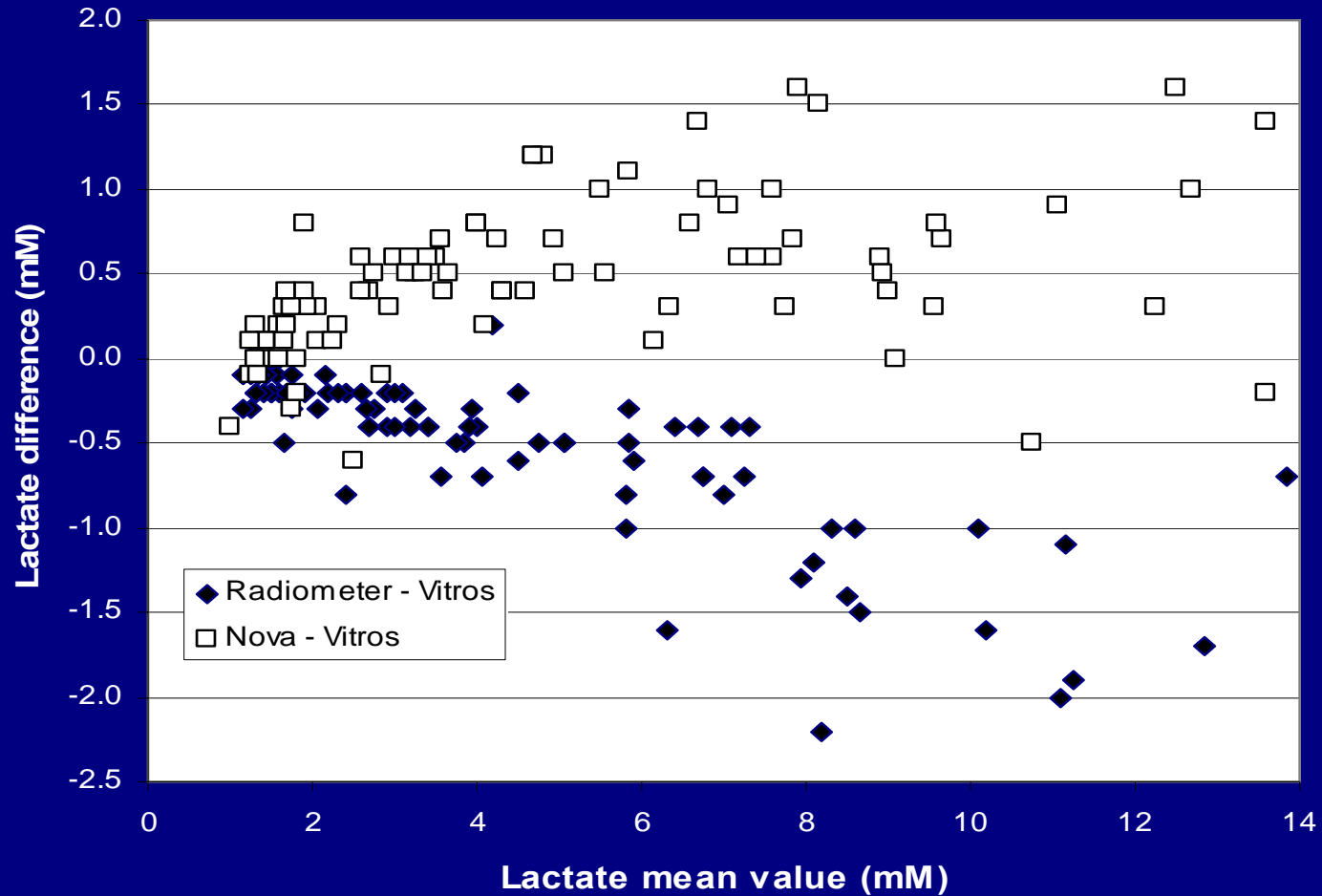
Method Comparison

Figure 1: Bland-Altman Plots of Integra and i-STAT vs. Vitros



Method Comparison

Figure 2: Bland-Altman Plots of Radiometer and Nova vs. Vitros

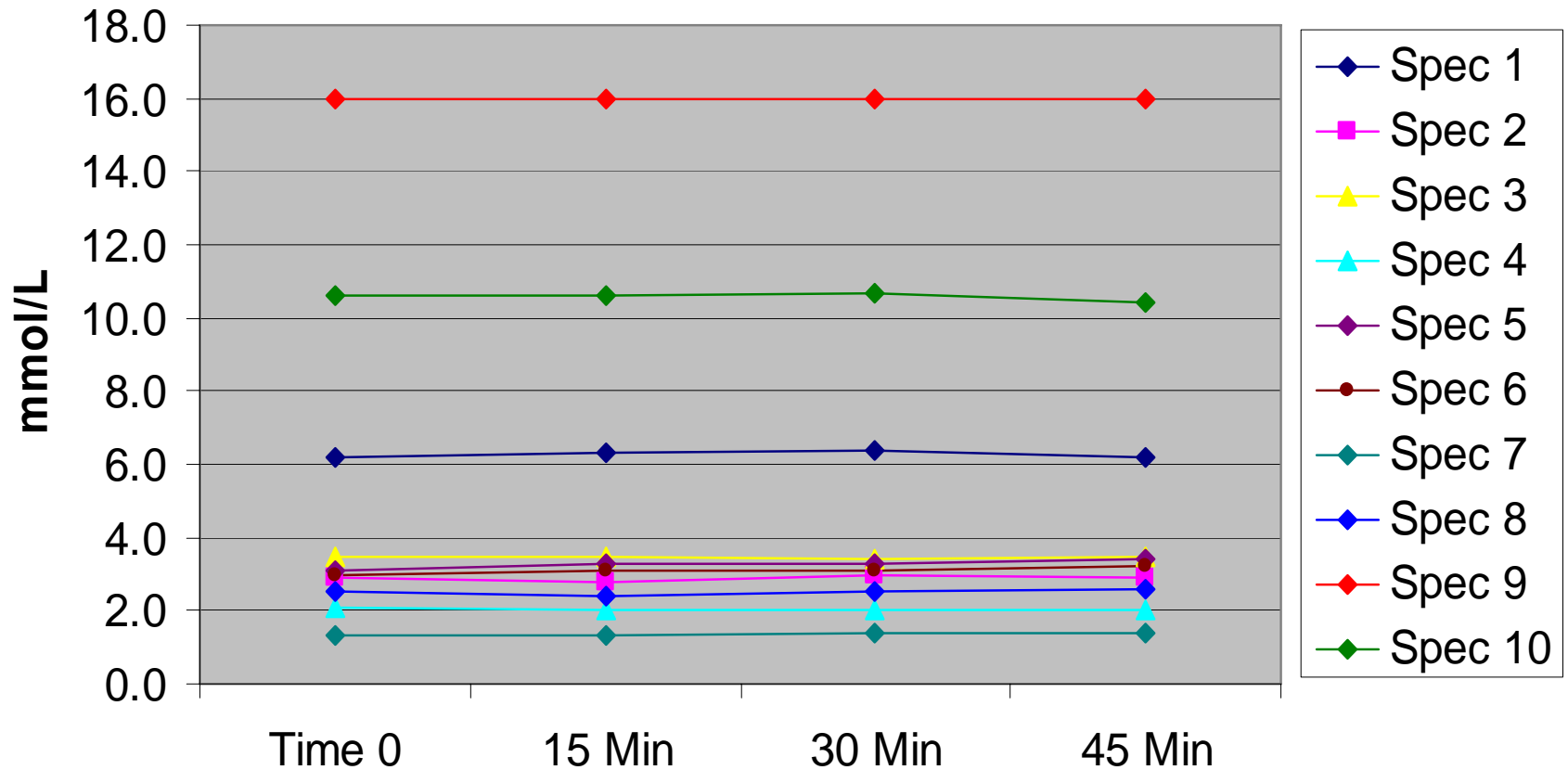


Stability

- Plasma on the Integra
- Whole blood on the Radiometer
- Whole blood was tested at 15 minute intervals up to 45 minutes
- Plasma was tested at 30 minute intervals up to 3 hours
- Iced samples (N = 10)

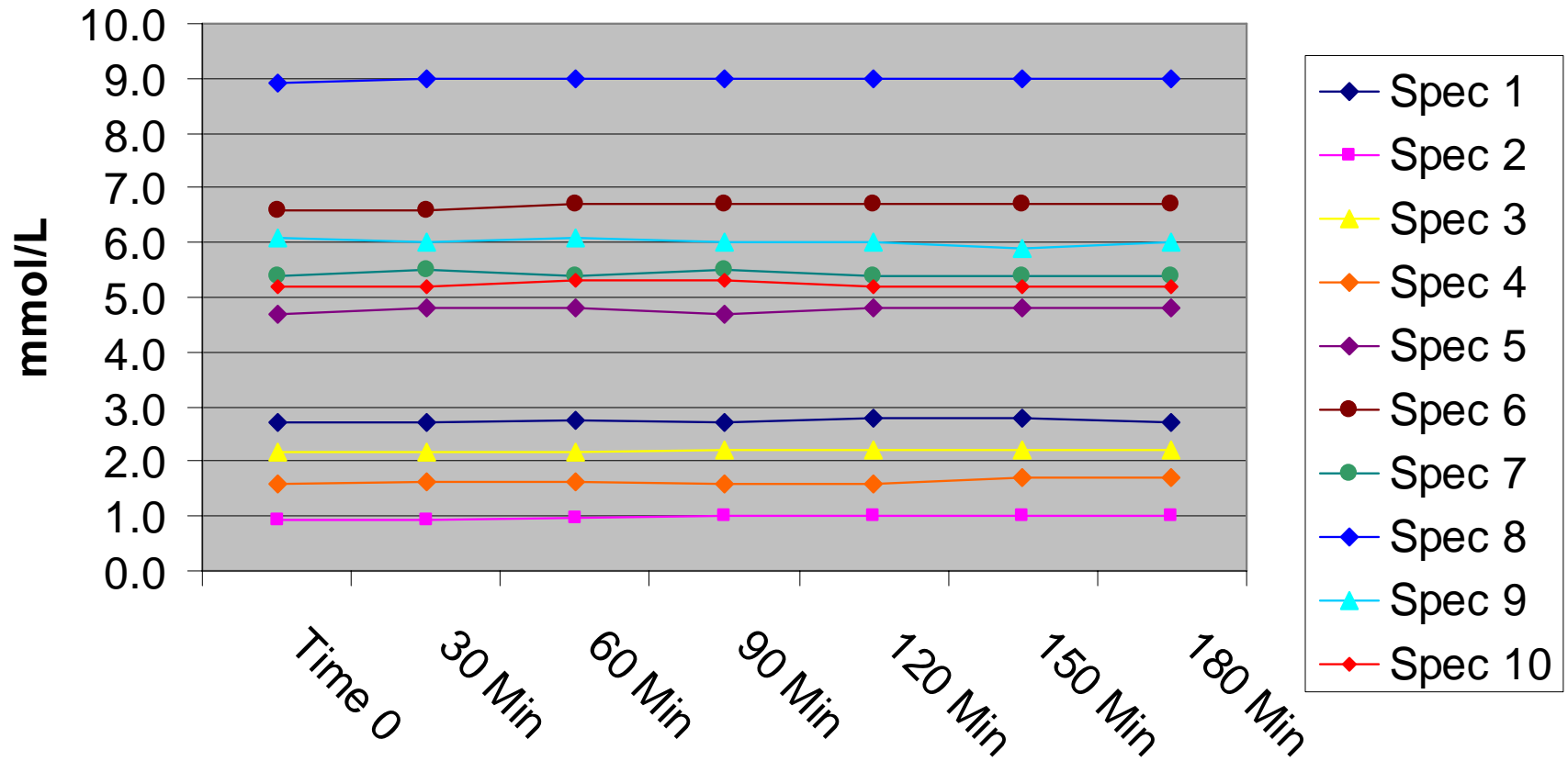
Whole Blood Stability

Lactate ABG Syringe Stability (Iced)



Plasma Stability

Lactate PST Stability (Iced)



Linearity

Analyzer	Measuring Range	Mean Recovery
Radiometer	0.0 – 26.0 mmol/L	96%
i-STAT CG4+	0.5 – 17.1 mmol/L	99%
Nova Lactate Meter	None available	
Roche Integra 400 Plus	0.0 – 32.7 mmol/L	99%

Precision

- Tested on all platforms by running control material 20 times over 7 – >10 days
 - Low control (0.8 – 1.7 mmol/L)
 - CV%: 1.7 – 3.3%, Nova 15.8%
 - Middle control (2.0 – 4.5 mmol/L)
 - CV%: 2.3 – 4.3%
 - High control (7.0 – 9.7 mmol/L)
 - CV%: 1.2 – 3.3%

Method Correlation

- Results were classified as either:
 - Low risk (≤ 2.2 mmol/L)
 - Intermediate risk (2.3 – 5.0 mmol/L)
 - High risk (> 5.0 mmol/L)
- Percent concordance was then calculated for each method (% of all samples that fell in the same risk category as the Vitros result).

% Concordance

Risk Category	Integra (89/90) 98.9%	Radiometer (85/90) 94.4%	i-STAT (85/90) 94.4%	NOVA (81/90) 90%
<2.2 (N = 29)	29	29	29	27
2.3 – 5.0 (N = 30)	29	27	27	24
>5.0 (N = 31)	31	29	29	31

Conclusions

- **The Roche Integra 400 Plus correlated best with the reference method, Vitros 250.**
- **The Radiometer ABL 725 and i-STAT methods report lower values than the Vitros or Integra, especially at lactate values over 6 mM.**

Conclusion

- **The Nova Lactate Plus method overestimates lactate at higher values.**
- **Follow-up testing with a central lab lactate (after initial POC) may give the false impression of increasing lactate values over time, thus suggesting worsening of the patient's condition.**

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