1

Benchmarking Laboratory Quality

Zoe C. Brooks

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Update: January 2016.
This study was presented at a Total Quality Management Symposium in Toronto in 2001. Nobody noticed.
The issues highlighted here persist today. Risk Management concepts and software remove the complexity of all these statistics and present the same knowledge in a format that is easy to understand.
Maybe now someone will notice. Zoe C. Brooks

(It has not been published prior to posting at ResearchGate January 2016.)

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Many thanks are extended to the participating laboratories:

Lab Name	City	Province/ State
Cape Breton Healthcare Complex	Sydney	NS
Children's Memorial Hospital, Chicago	Chicago	IL
Gamma-Dynacare Brantford	Brantford	ON
Gamma-Dynacare London	London	ON
Gamma-Dynacare Ottawa	Ottawa	ON
Hamilton Health Sciences: Henderson Campus	Hamilton	ON
Joseph Brant Memorial Hospital	Burlington	ON
Kaiser Permanente Regional Lab	Berkley	CA
Laboratorio Analisi Chimico Cliniche- Azienda Ospedale Careggi	Firenze	Italy
London Health Services Centre (Westminster Campus)	London	ON
London Health Services Centre (University Campus)	London	ON
London Health Services Centre (Victoria Campus South Street)	London	ON
MDS Laboratories	Sudbury	ON
Phenix Regional Hospital	Pheonix City	AB
St Paul's General Hospital	Vancouver	BC
Swedish Covenent, Chicago	Chicago	IL
The Hospital for Sick Children	Toronto	ON
Tillsonburg District Memorial Hospital	Tillsonburg	ON
Toronto East General Hospital	Toronto	ON
Toronto Medical Labs	Toronto	ON
Whitehorse General Hospital	Whitehorse	YK

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Many thanks are extended to the control laboratories

These laboratories have applied the "Performance-Driven Quality Control" process for two to ten years.

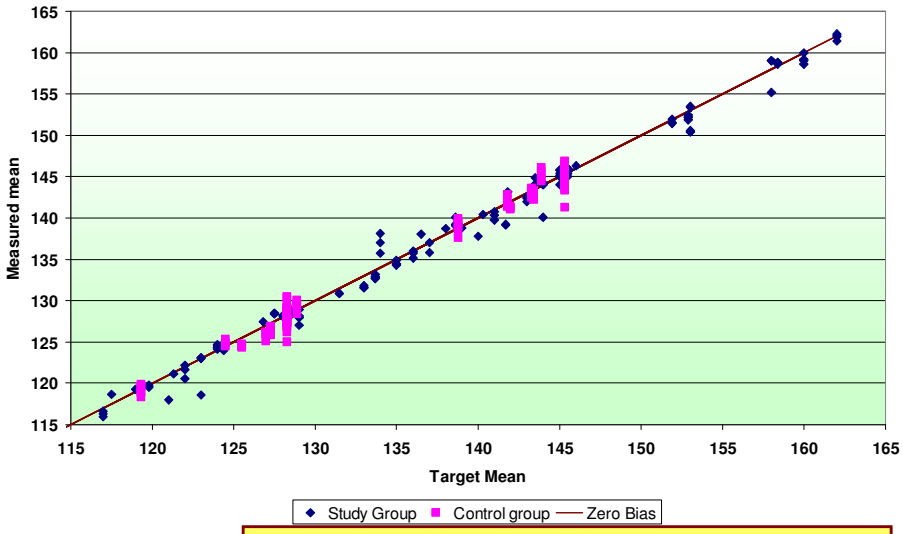
Ansen General Hospital	Iroquois Falls	ON
Bingham Memorial Hospital	Mattheson	ON
Hornepayne Community Hospital	Hornepayne	ON
Lady Minto Hospitial	Cochrane	ON
Notre Dame Hospital	Hearst	ON
Sensenbrenner Hospital	Sensenbrenner Hospital	ON
Smooth Rock Falls Hospital	Smooth Rock Falls	ON
Fort MacLeod Hospital	Fort MacLeod	AB
Pincher Creek Hospital	Pincher Creek	AB
Taber Hospital	Taber	AB
Crowsnest Pass Hospital	Blairmore	AB
Cardston Hospital	Cardston	AB
Lethbridge Regional Hospital	Lethbridge	AB

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Bias = (Measured Mean – Target)

Sodium

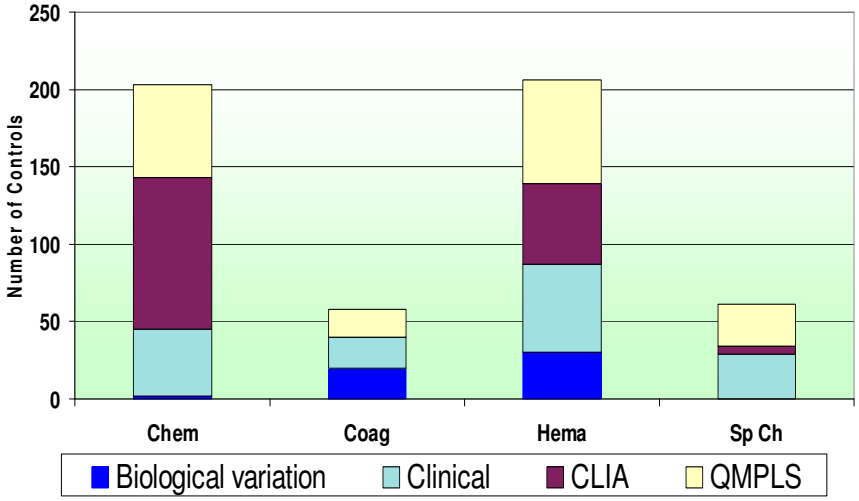


Each dot = 1 QC sample from one lab/method for 1 month

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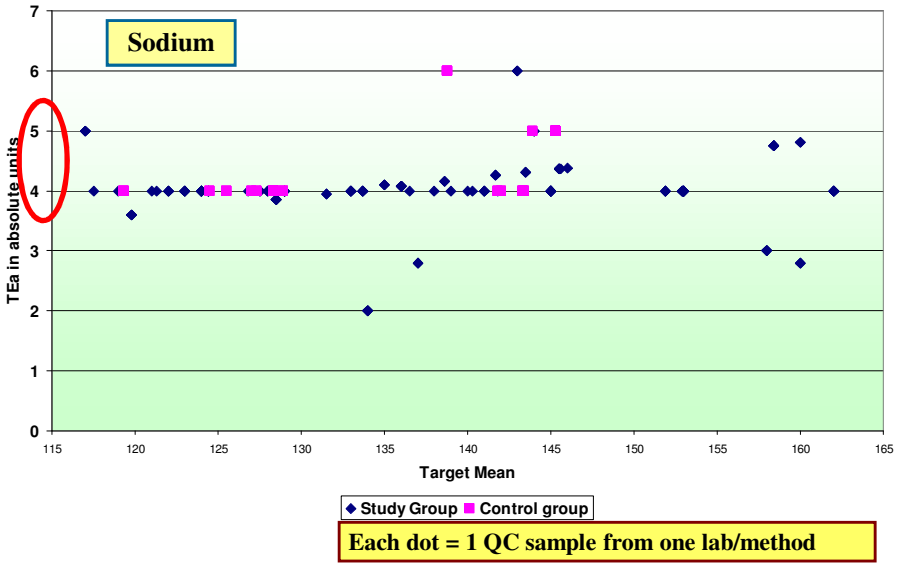
TEa Source by Department



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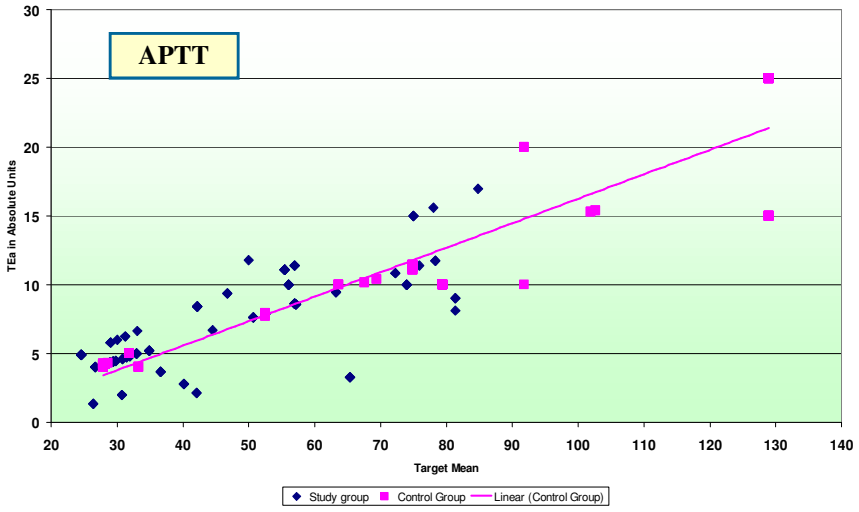
TEa = Criteria to measure effectiveness of a process



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7

TEa = Total Error allowed =
Criteria to measure effectiveness of a process

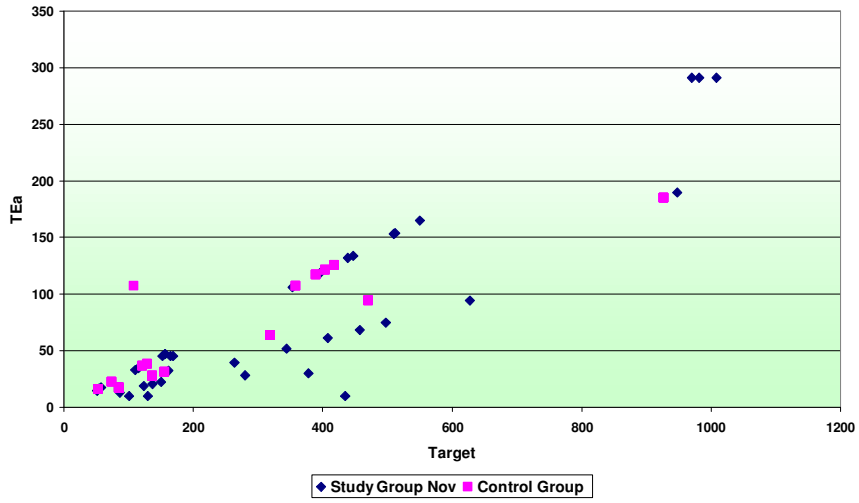


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Each dot = 1 QC sample from one lab/method for 1 month

8

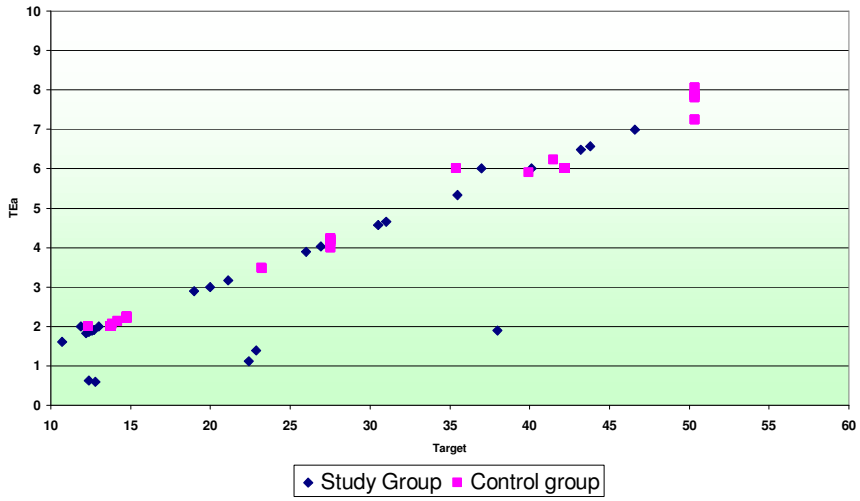
CK TEa limits



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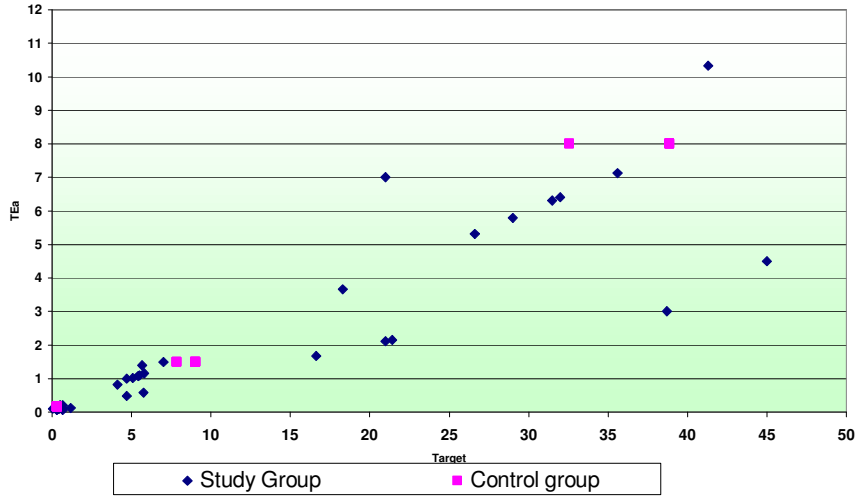
Prothrombin Time TEa limits



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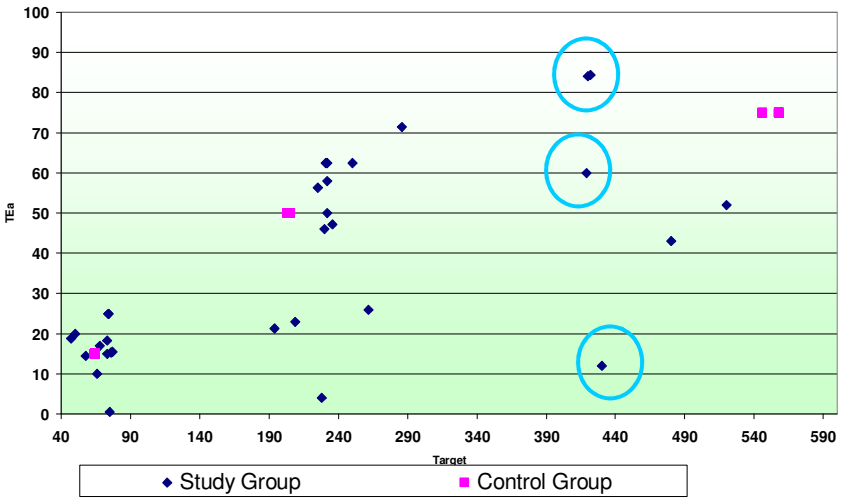
10

TSH TEa limits



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11 **Platelets TEa limits**

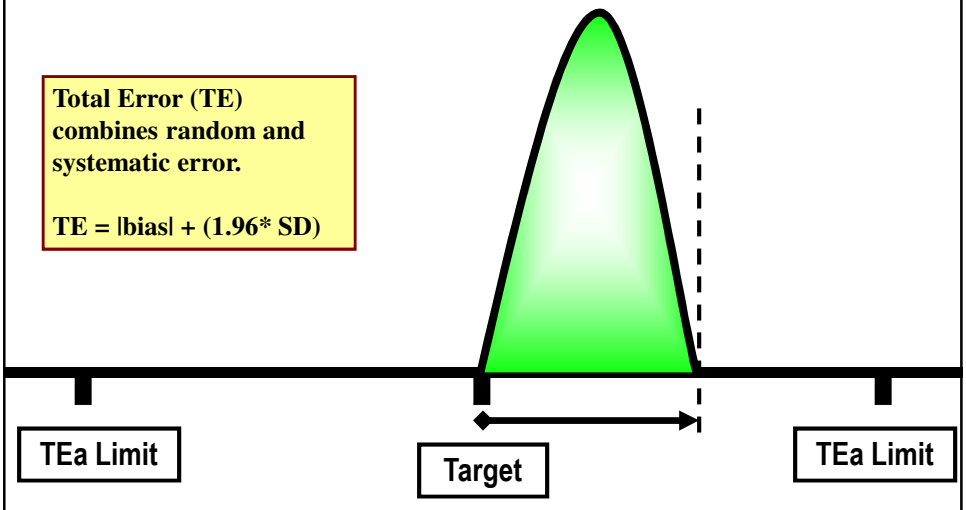


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12 **Total Error is a metric that indicates how far results fall from the True/Target value**

Total Error (TE) combines random and systematic error.

TE = |bias| + (1.96* SD)



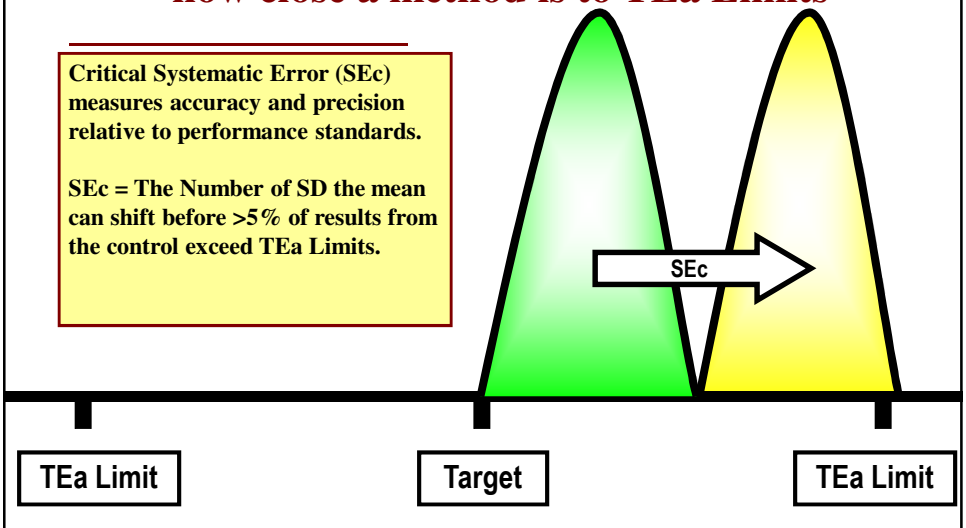
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SEc is a metric that indicates how close a method is to TEa Limits

Critical Systematic Error (SEc) measures accuracy and precision relative to performance standards.

SEc = The Number of SD the mean can shift before >5% of results from the control exceed TEa Limits.

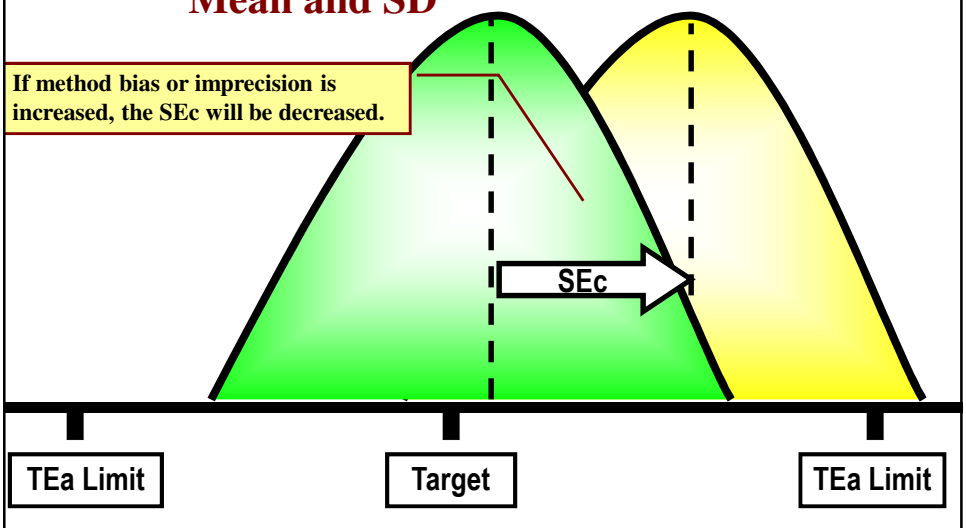


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SEc varies with Target, TEa, Mean and SD

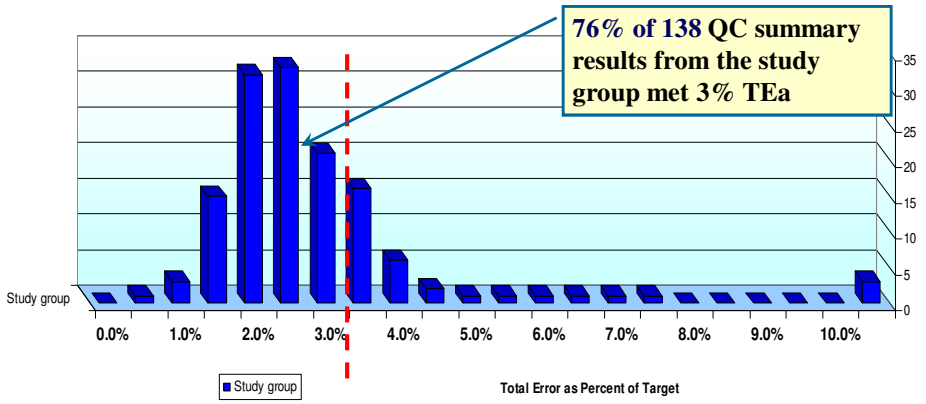
If method bias or imprecision is increased, the SEc will be decreased.



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Total Error as Percent - Sodium



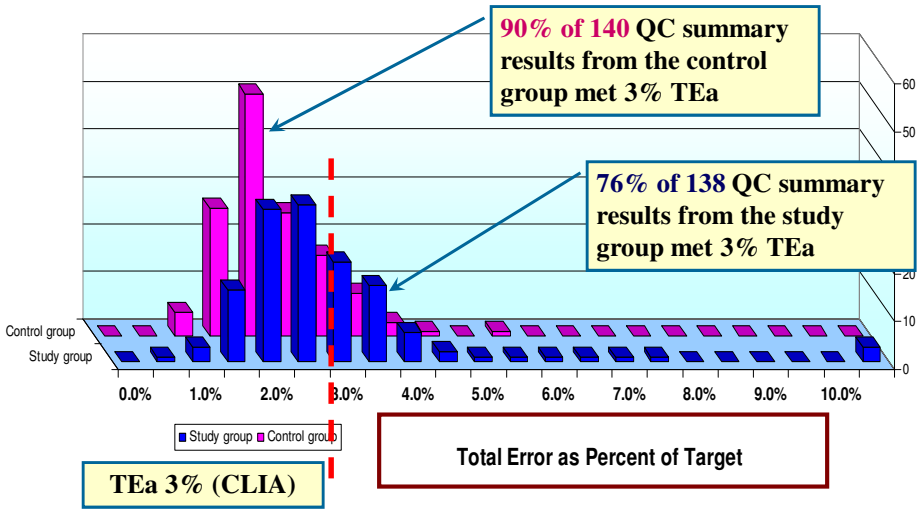
TEa 3% (CLIA)

One Bar = percent of QC samples at each TEa level. Below TEa line 'passes'

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Total Error as Percent - Sodium

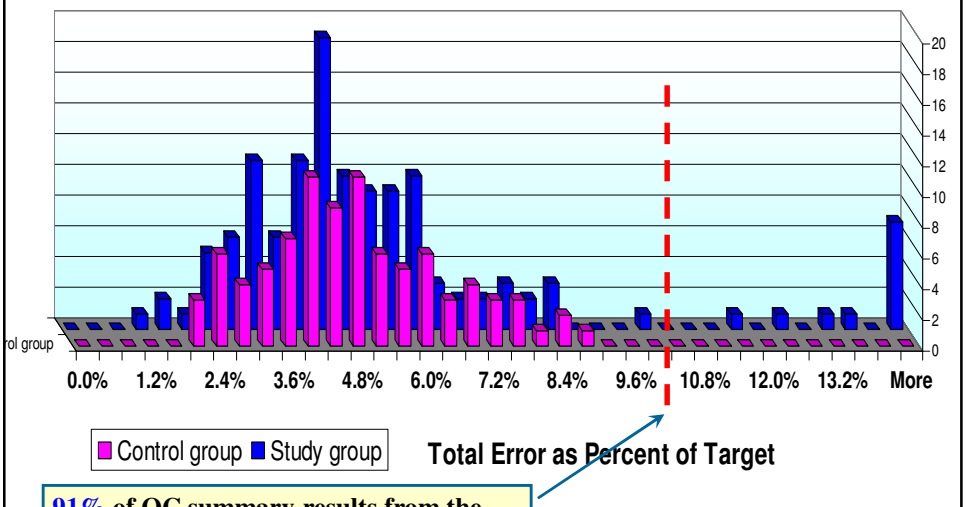


TEa 3% (CLIA)

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Total Error as Percent - Cholesterol



91% of QC summary results from the Study group and **100%** from the Control Group met 10% TEa from CLIA.

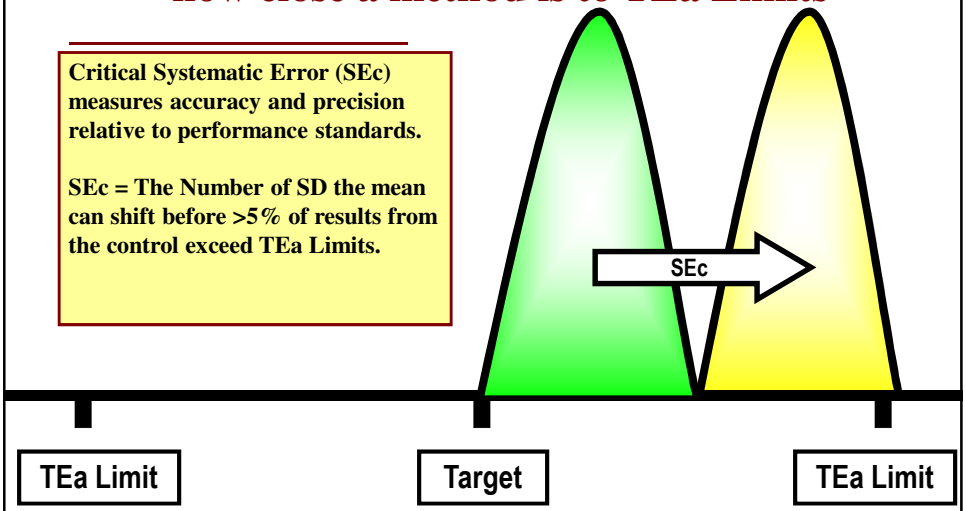
© Z Brooks 2001 -2016

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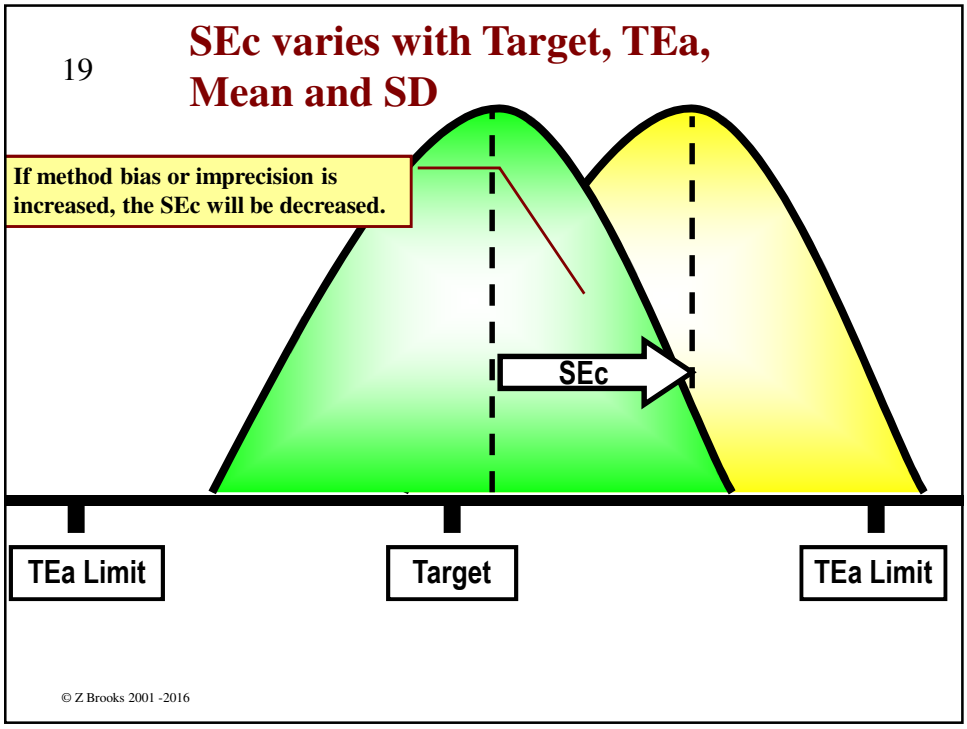
SEc is a metric that indicates how close a method is to TEa Limits

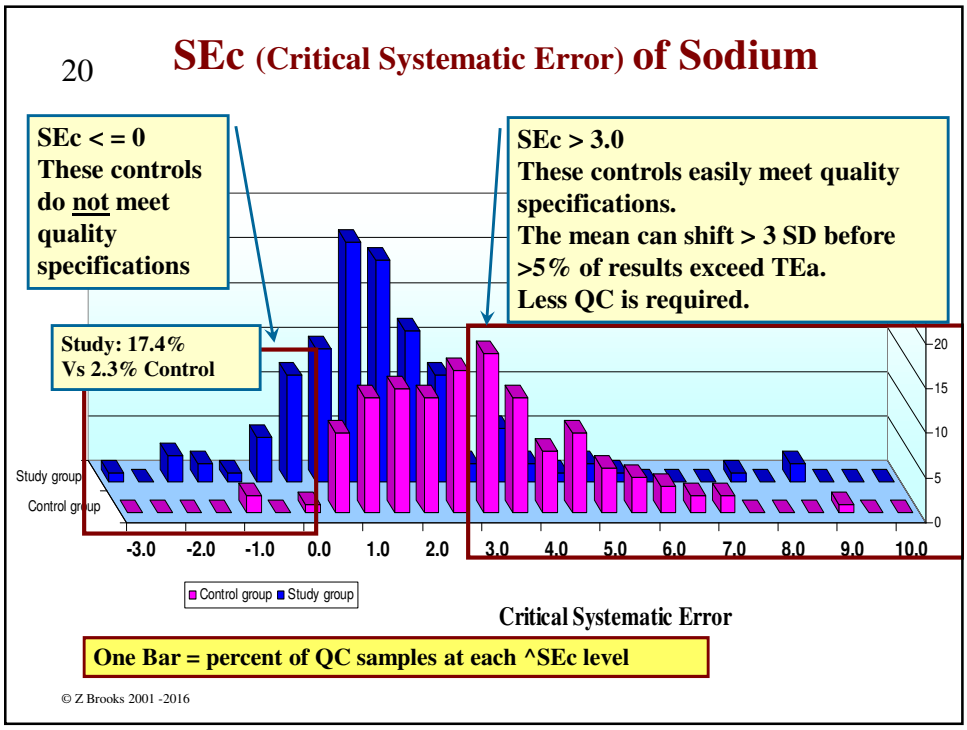
Critical Systematic Error (SEc) measures accuracy and precision relative to performance standards.

SEc = The Number of SD the mean can shift before >5% of results from the control exceed TEa Limits.



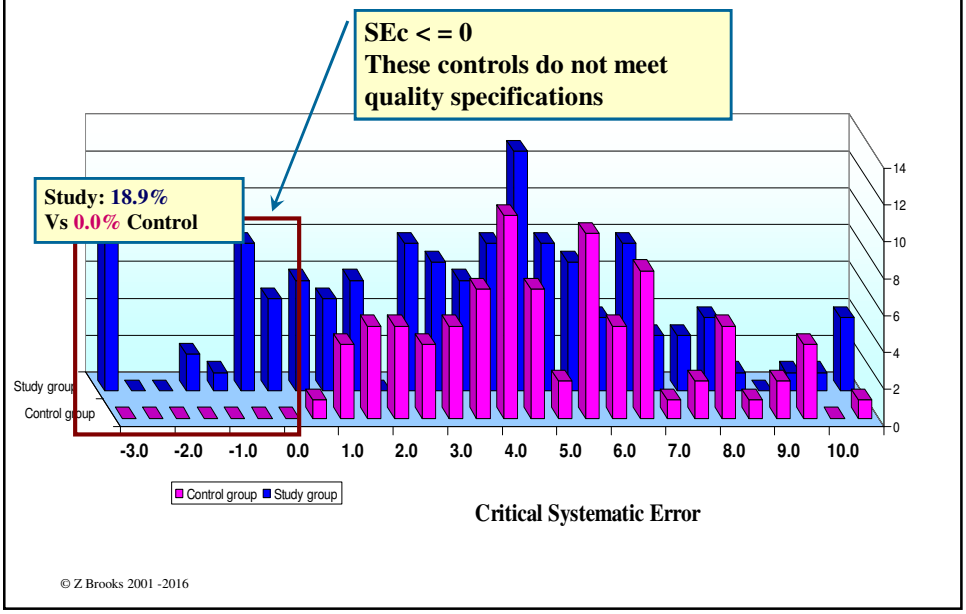
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SEc varies with Target, TEa, Mean and SD
If method bias or imprecision is increased, the SEc will be decreased.
SEc
TEa Limit
Target
TEa Limit
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SEc (Critical Systematic Error) of Sodium
SEc < = 0
These controls do not meet quality specifications
SEc > 3.0
These controls easily meet quality specifications.
The mean can shift > 3 SD before >5% of results exceed TEa.
Less QC is required.
Study: 17.4%
Vs 2.3% Control
Study group
Control group
-3.0 -2.0 -1.0 0.0 1.0 2.0 3.0 4.0 5.0 6.0 7.0 8.0 9.0 10.0
0 5 10 15 20
Control group Study group
Critical Systematic Error
One Bar = percent of QC samples at each ^SEc level
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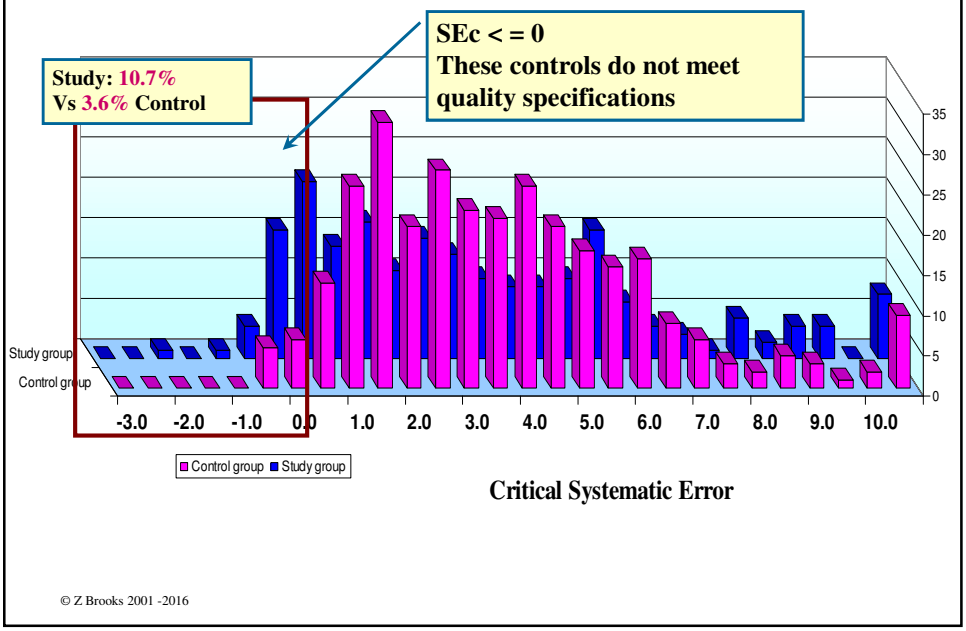
SEc (Critical Systematic Error) of Cholesterol



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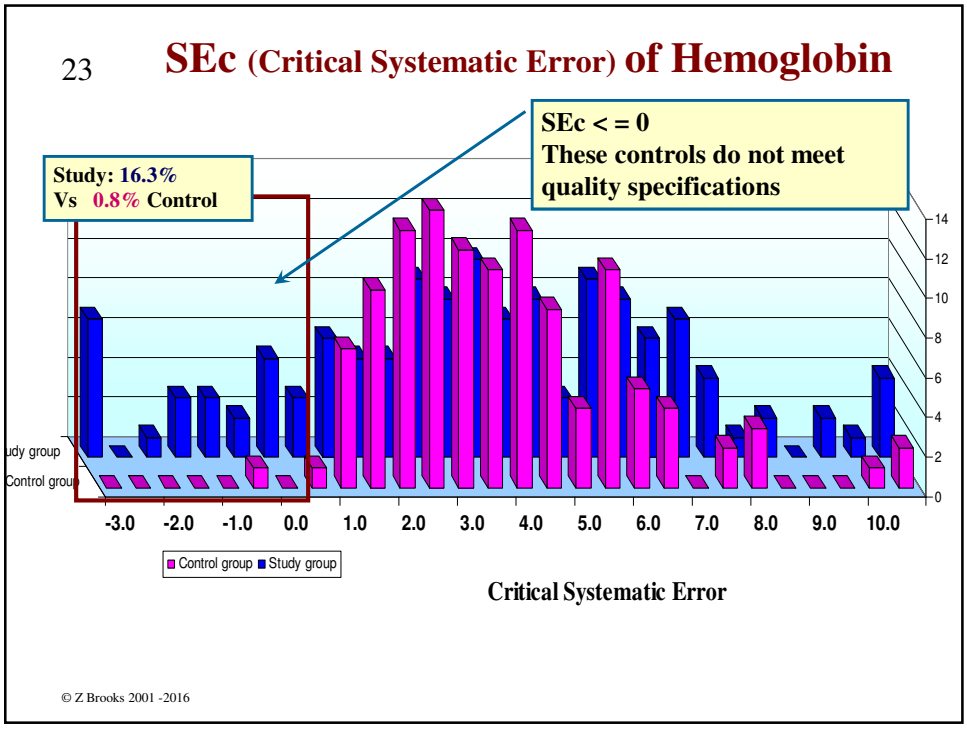
SEc (Critical Systematic Error) of PT and APTT



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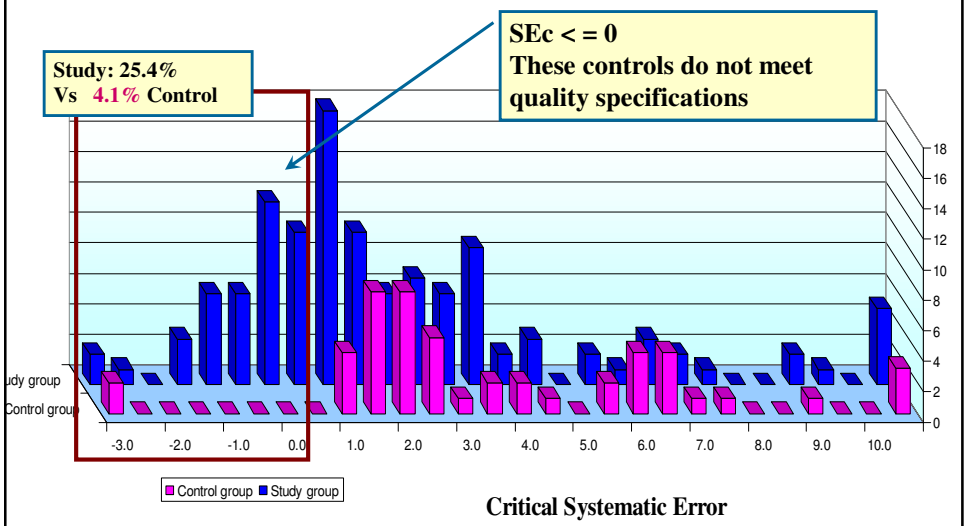
SEc (Critical Systematic Error) of Hemoglobin



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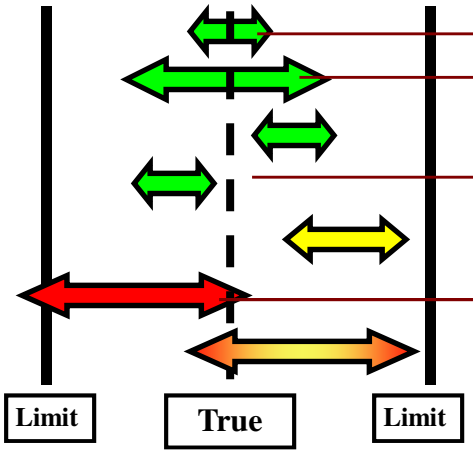
SEc (Critical Systematic Error) of TSH



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Laboratories used a now discontinued software program created by Zoe Brooks to create Z-Bars© to display performance



Accurate methods are centered about the target value

Precision is indicated by the width of the Z-Bar©

Position indicates Bias

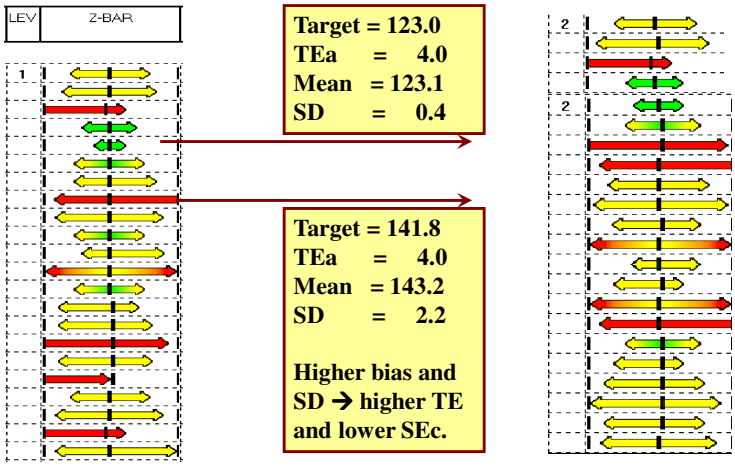
Z-Bars© are color coded like traffic lights: Red = problem

One Z-Bar
= 1 QC sample for 1 month

26

Z-Bars© show variation in TE and SEc compared to the Target and TEa

Sodium



Target = 123.0
TEa = 4.0
Mean = 123.1
SD = 0.4

Target = 141.8
TEa = 4.0
Mean = 143.2
SD = 2.2

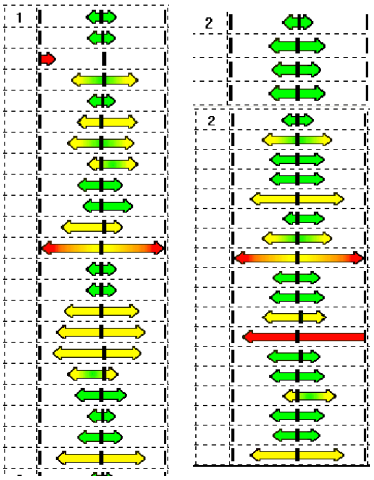
Higher bias and SD → higher TE and lower SEc.

One Z-Bar = 1 QC sample for 1 month

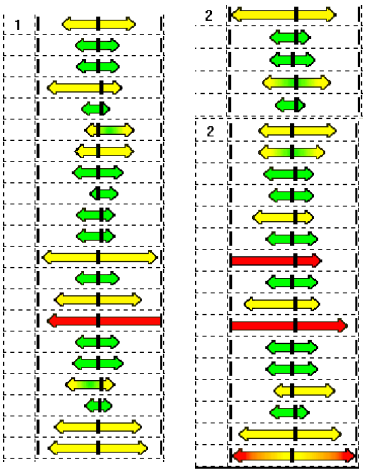
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27 **Z-Bars© for study group Nov 2000**

Potassium



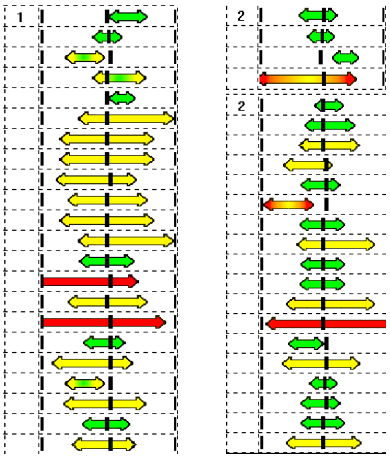
Calcium



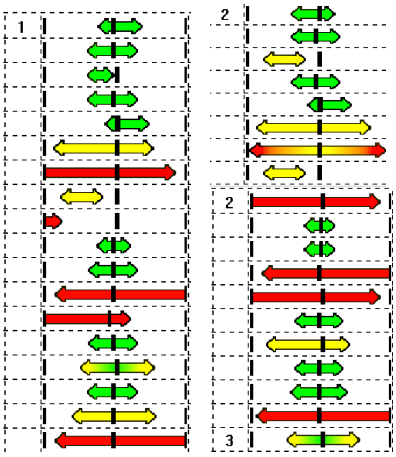
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28 **Z-Bars© for study group Nov 2000**

Glucose



Cholesterol

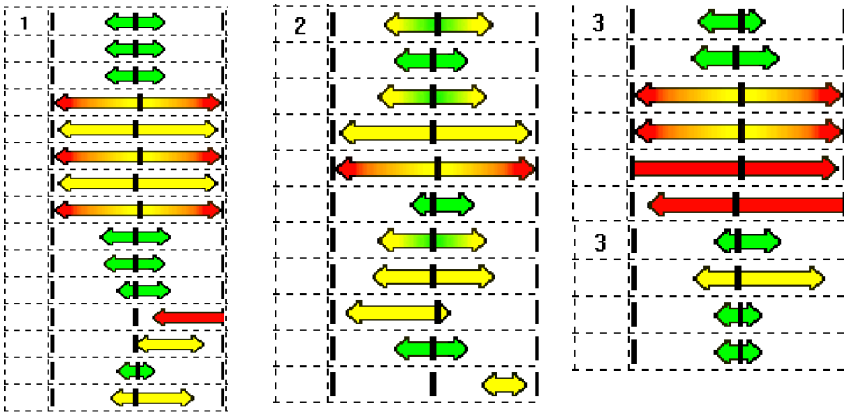


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Z-Bars© for study group Nov 2000

APTT

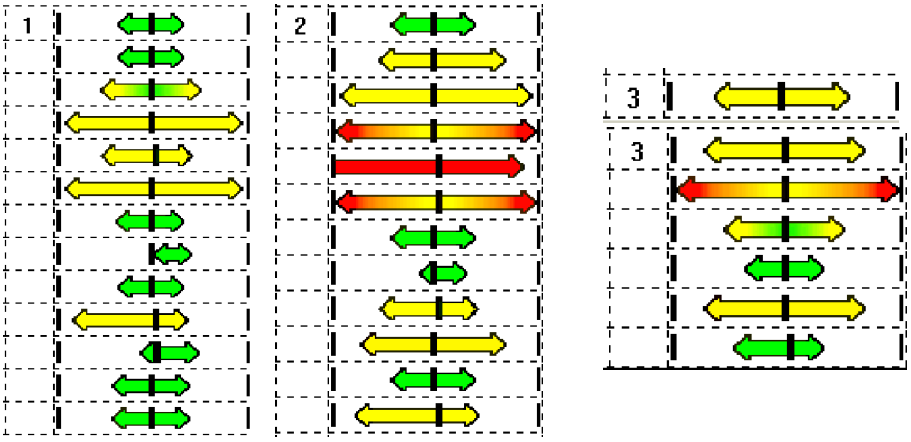


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30

Z-Bars© for study group Nov 2000

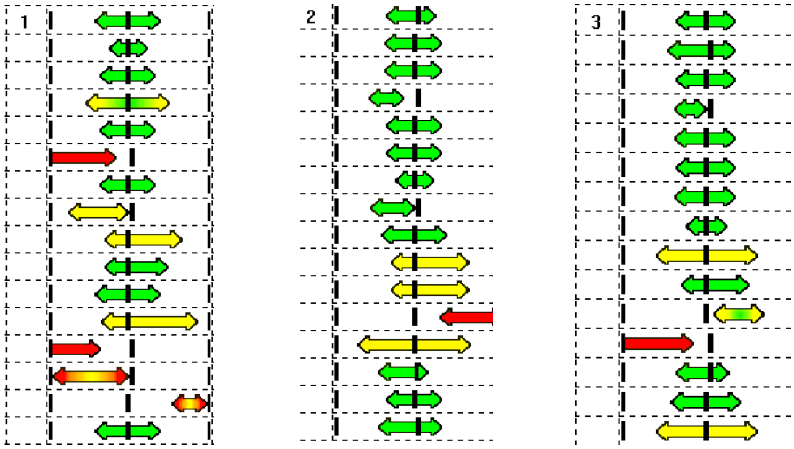
Prothrombin Time



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31 **Z-Bars© for study group Nov 2000**

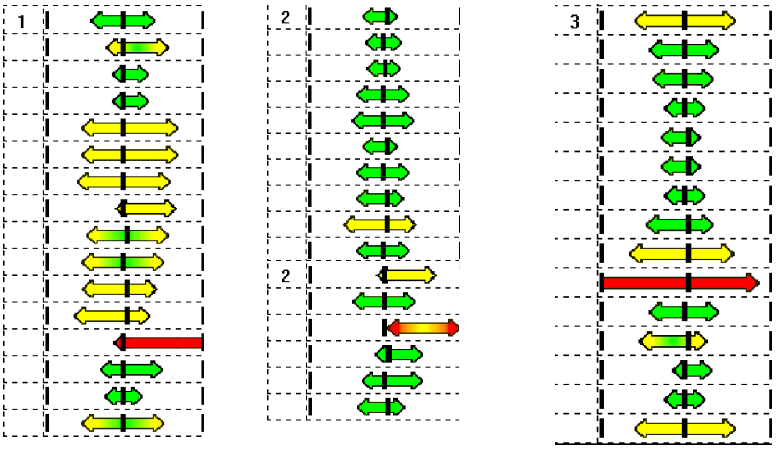
Hemoglobin



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32 **Z-Bars© for study group Nov 2000**

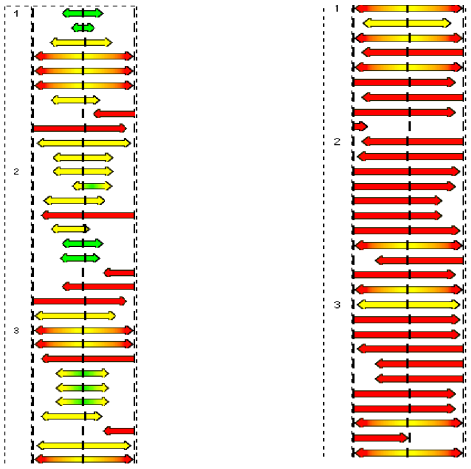
WBC



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33 **Z-Bars© for study group Nov 2000**

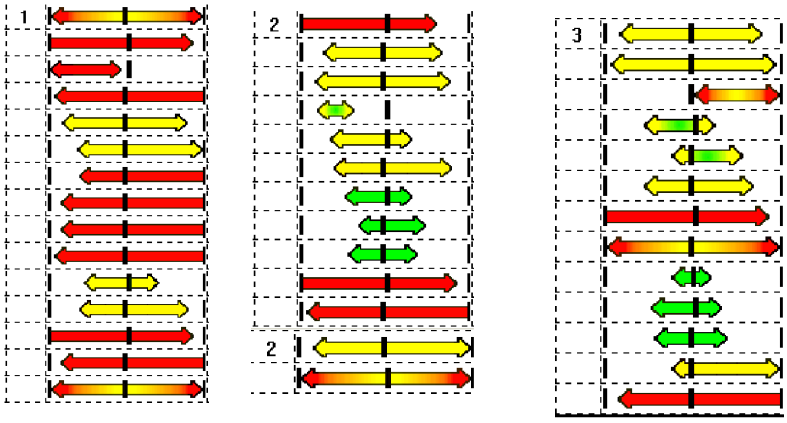
Eosinophil Absolute Count and Percentage



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34 **Z-Bars© for study group Nov 2000**

Digoxin

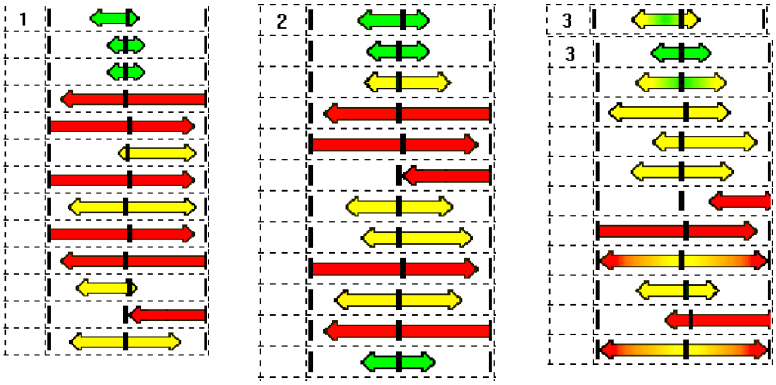


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Z-Bars© for study group Nov 2000

TSH

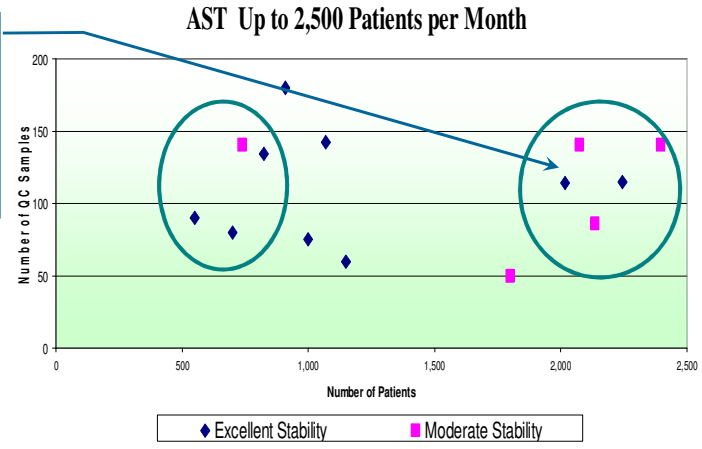


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Ratio of QC Samples to Patient Samples

The patient test volume is ~4x higher; QC test frequency is the same

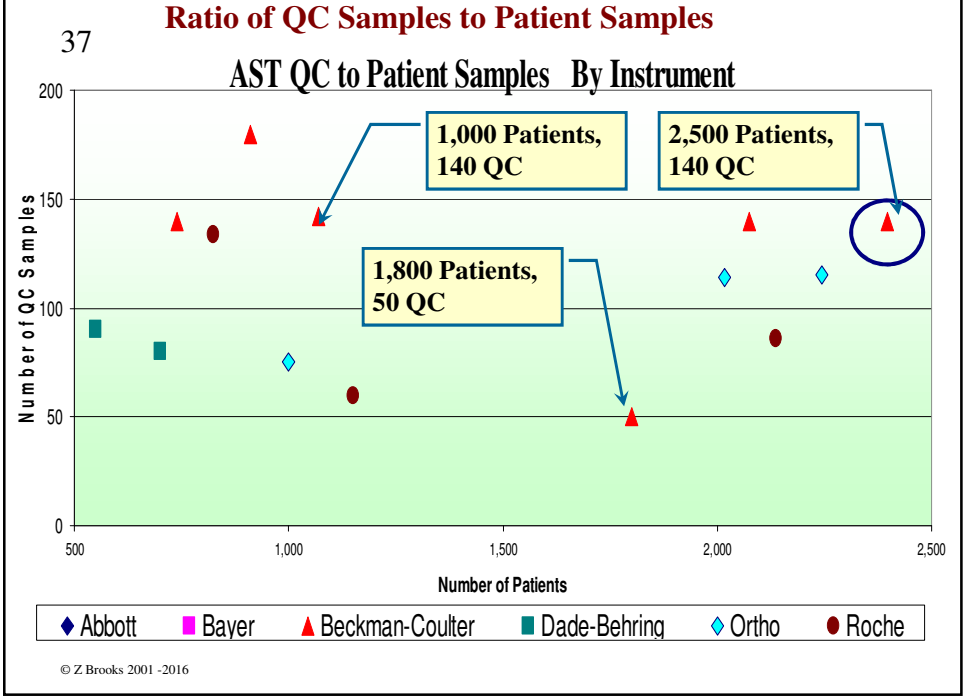


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Each dot = 1 QC sample from one lab/method for 1 month

Ratio of QC Samples to Patient Samples

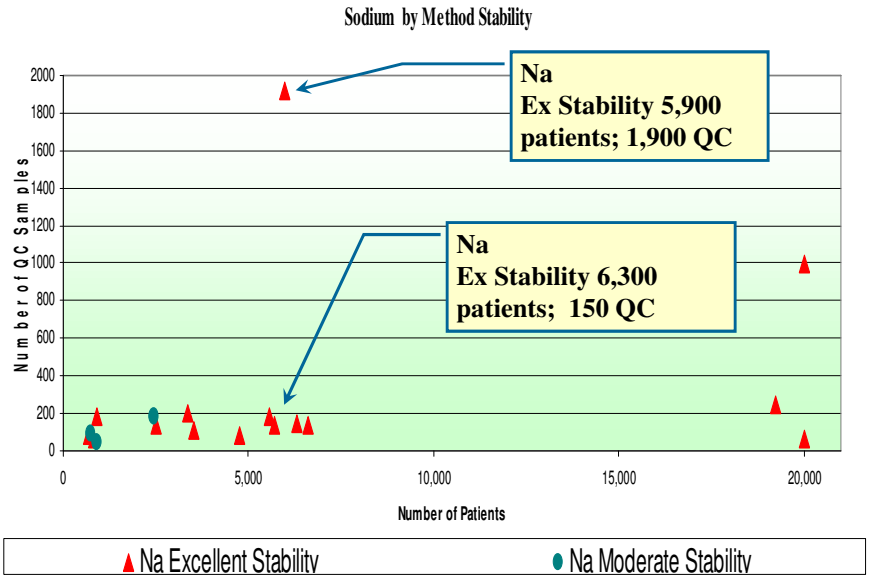
37



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Ratio of QC Samples to Patient Samples

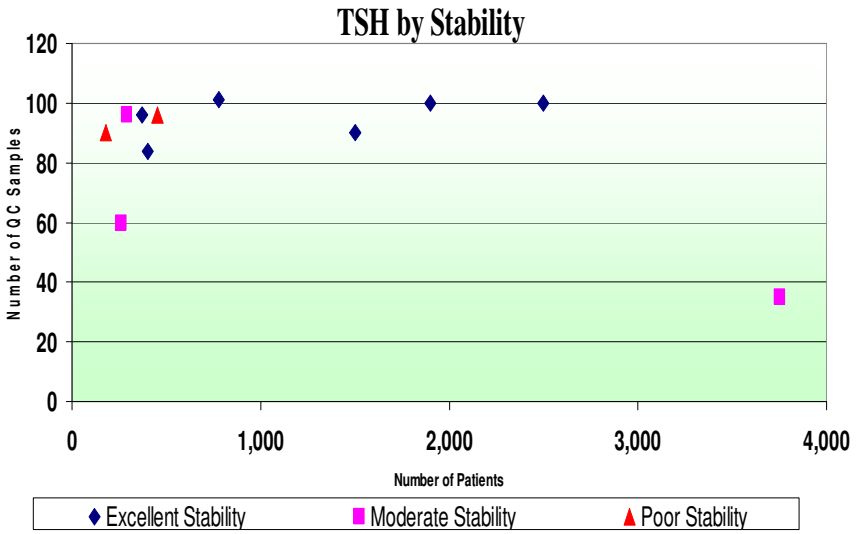
38



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39

Ratio of QC Samples to Patient Samples



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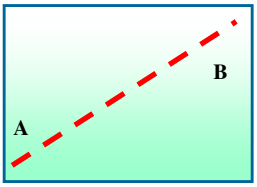
40

Does the observed SEc affect the selection of QC rules?

We can increase error detection when SEc is low by increasing the number of QC samples or frequency of QC runs.

Thus we would expect that the ratio of patient samples to QC samples would be INVERSELY proportional to SEc.

A control that can only shift 1 SD (A) requires more frequent QC than one that can shift 10 SD before exceeding quality specifications. (B)



SEc zero to > 10

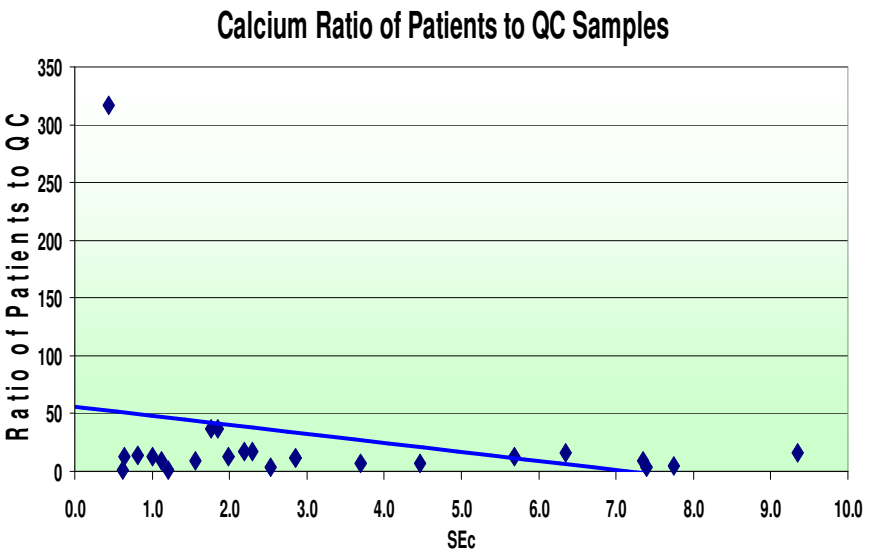
A = 10 pts/QC

B = 100 pts/QC

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Do labs test more QC samples/ patient when SEc is low?

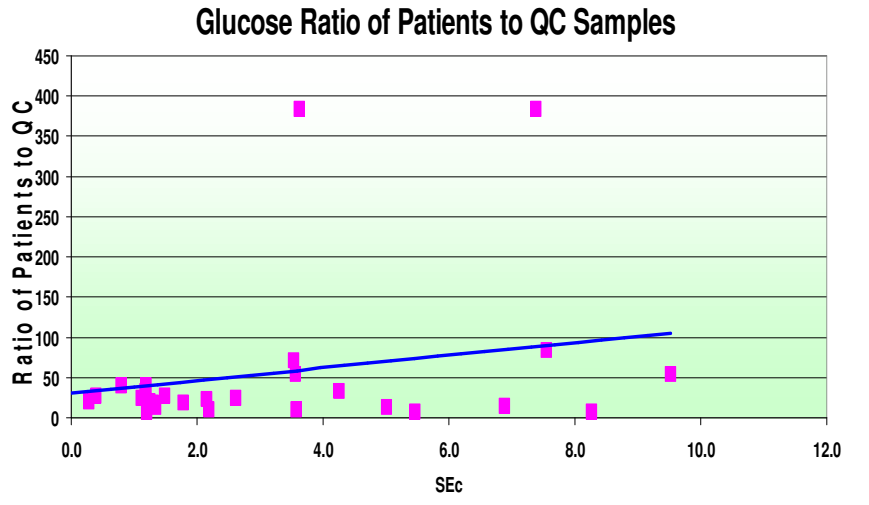


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Each dot = 1 QC sample from one lab/method for 1 month

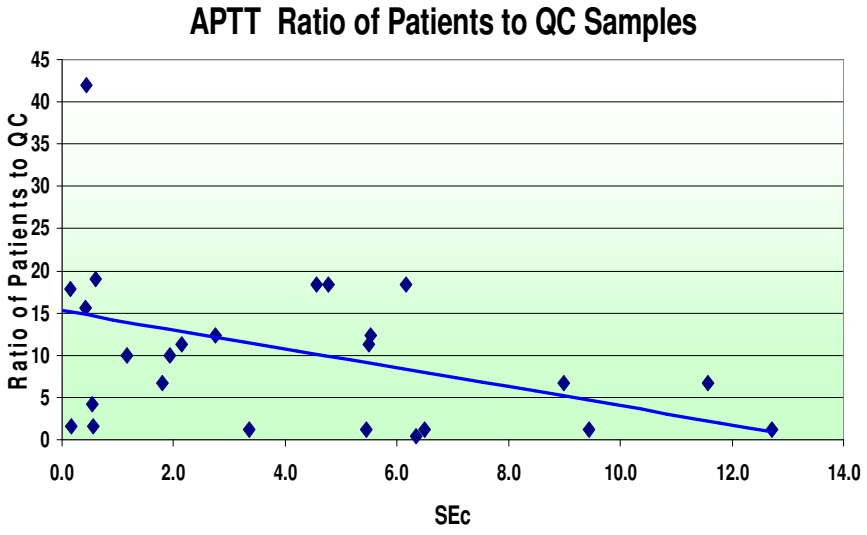
42

Do labs test more QC samples/ patient when SEc is low?



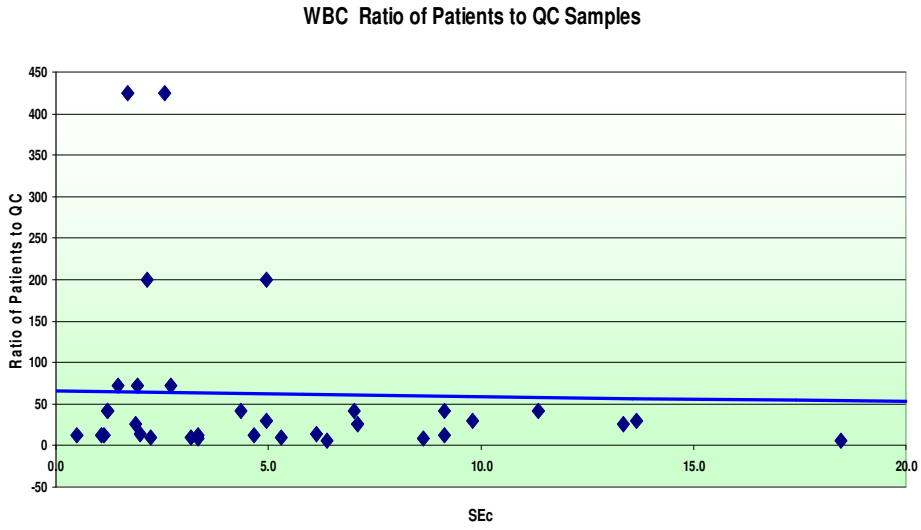
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43 **Do labs test more QC samples/ patient when SEc is low?**



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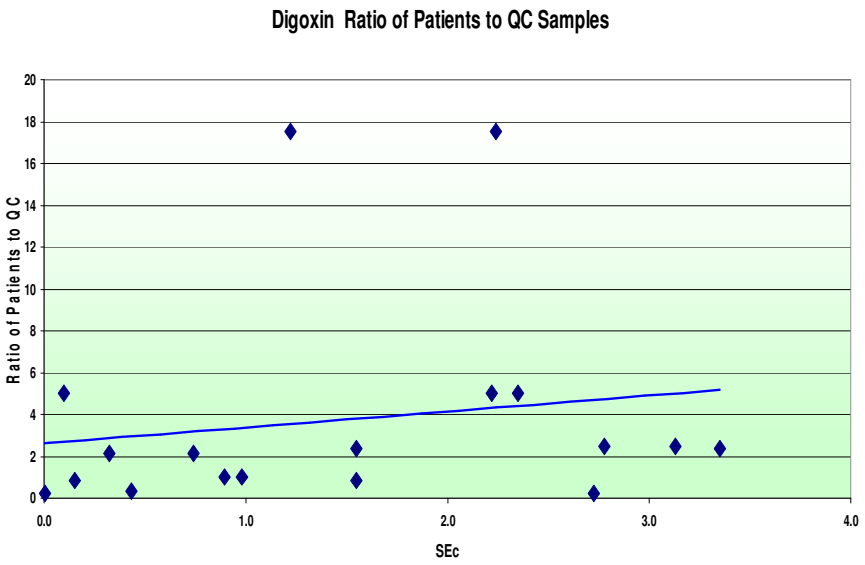
44 **Do labs test more QC samples/ patient when SEc is low?**



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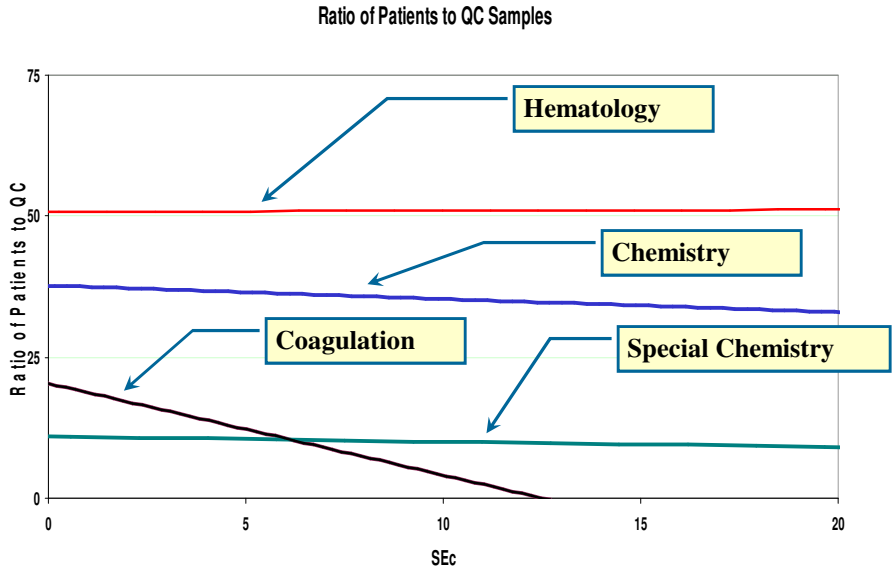
Do labs test more QC samples/ patient when SEc is low?



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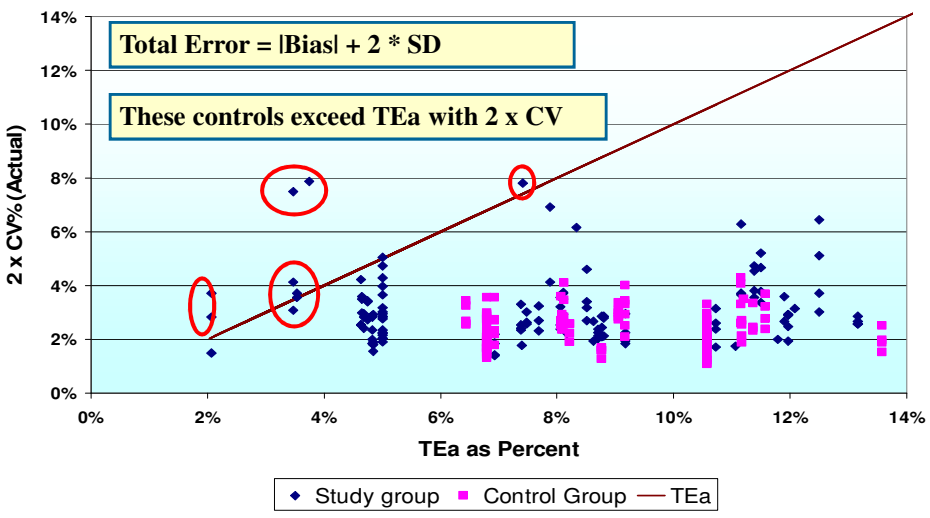
Do labs test more QC samples/ patient when SEc is low?



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Calcium – Compare 2xCV to TEa as %

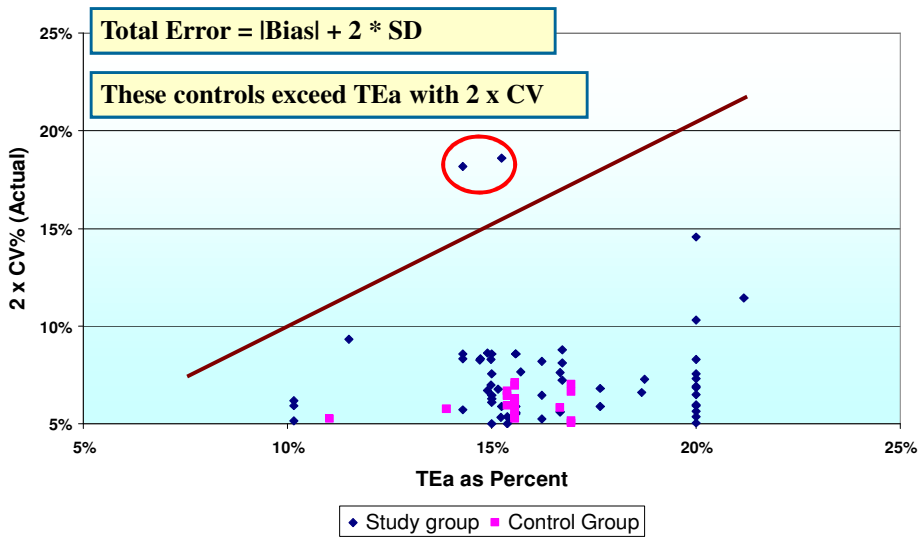


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Each dot = 1 QC sample from one lab/method for 1 month

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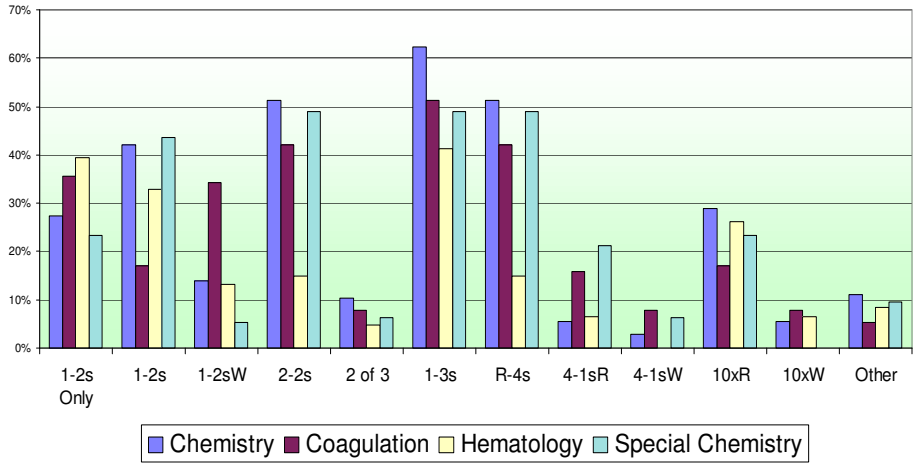
WBC – Compare 2xCV to TEa as %



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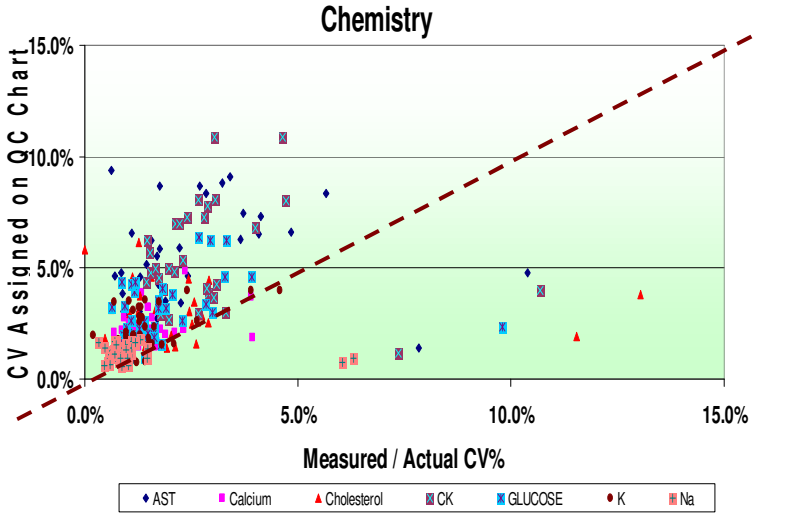
QC Rules by Percent of Controls



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Ratio of Observed to Assigned SD/CV

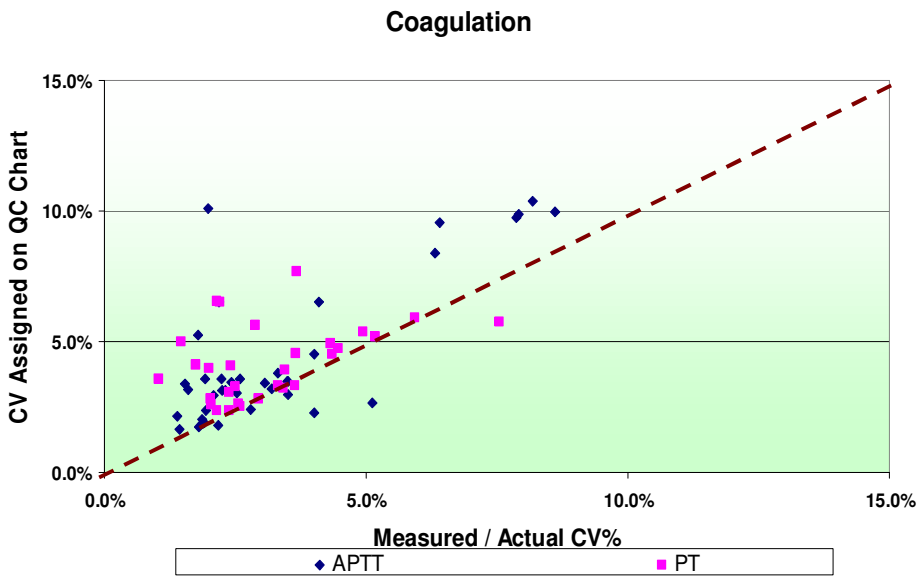


Each dot = 1 QC sample from one lab/method for 1 month

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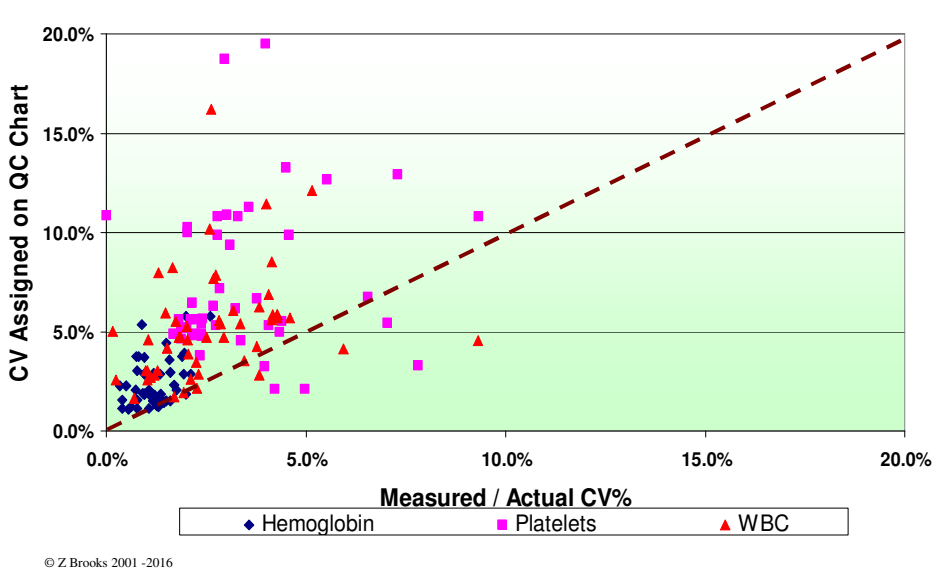
Ratio of Observed to Assigned SD/CV



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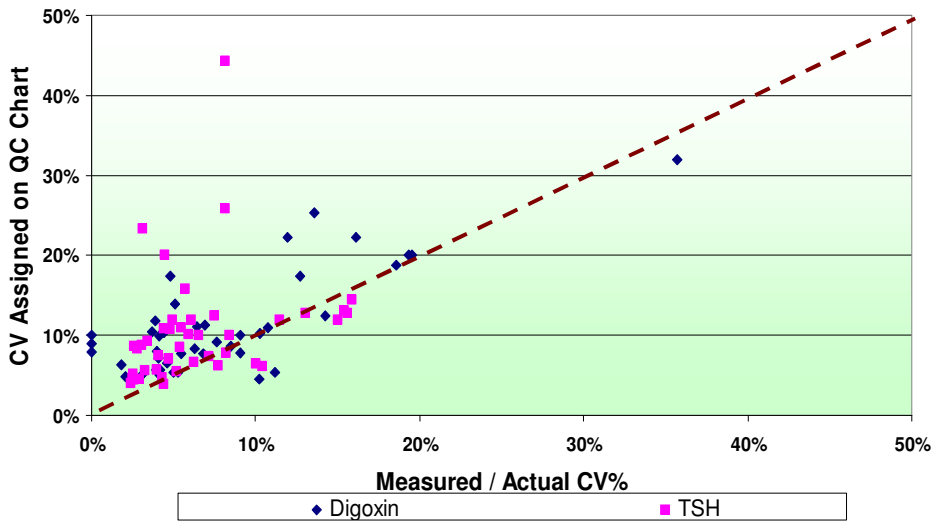
Ratio of Observed to Assigned SD/CV



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Ratio of Observed to Assigned SD/CV



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Comments January 16, 2016

This body of knowledge existed 10 years ago. Little (if any) improvement has been made in the effectiveness of quality control processes or, surprisingly, in the risk levels of medically-unreliable results.

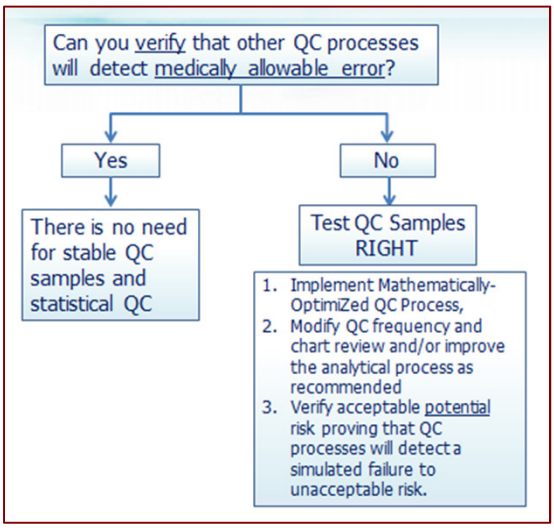
Risk Metrics, Risk Graphics and the process of Mathematically-OptimiZed Risk Evaluation (M.O.R.E.) transform this overwhelming amount of data into meaningful information with recommendations. This new perspective creates a new paradigm in quality management.

S.Q.C.	M.O.R.E.
A calculation	A process
4 variables	11 Risk Drivers
Creates a metric - sigma (replaced ^SEc) *^SEc is a far better metric for labs. Margin for Error is better than both.*	Manages Risk 34 Risk Metrics 5 Benefits 14 Clear text evaluations 15 Recommendations

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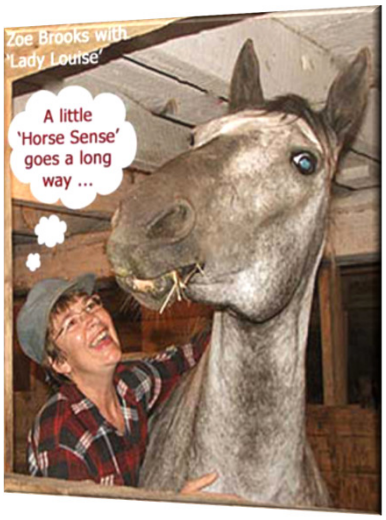
Mathematically-OptimiZed Risk Evolution virtually automates – and verifies- the QC process.



Please join me to explore this new paradigm.

zoe@awesome-numbers.org

www.awesome-numbers.org



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