REAL WORLD AND REAL TIME ASSESSMENT OF YOUR LAB'S QUALITY CONTROL EFFECTIVENESS:

FINDING AND FIXING THE UNRECOGNIZED COST OF POOR QUALITY

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LEARNING OBJECTIVES:

- Identify the costs of poor quality
- Explain the value of continual monitors
- Describe how to prepare your lab for IQCP regulations

WHAT IS QUALITY?

- Oxford Dictionary
  - ***Quality*** is the standard of something as measured against other things of a similar kind; the degree of excellence of something
- Merriam-Webster
  - ***Quality*** is how good or bad something is; a degree of excellence

QUALITY IN THE LABORATORY

- CAP definitions
  - ***Quality control*** is an integral component of quality assurance and is the aggregate of processes and techniques to ***detect, reduce, and correct deficiencies in an analytical process.***
  - ***Quality assurance*** in pathology and laboratory medicine is the practice of assessing performance in all steps of the laboratory testing cycle including ***pre-analytic, analytic, and post-analytic phases*** to promote excellent outcomes in medical care.
  - ***Quality improvement*** is the practice of continuously assessing and adjusting performance using statistically and scientifically accepted procedures.

QUALITY IN THE LABORATORY

Table 8. Aggregate Percentage of Most Important Laboratory Service Category

Service Category*	Respondents, No. (%) (n = 3754)
Quality/reliability of results	1191 (31.7)
Routine test TAT	554 (14.8)
Inpatient stat test TAT	455 (12.1)
Test menu adequacy	409 (10.9)
Outpatient stat test TAT	361 (9.6)
Accessibility of pathologists	160 (4.3)
Critical value notification	152 (4.0)
Clinical report format	90 (2.4)
Accessibility of laboratory staff	90 (2.4)
Esoteric test TAT	81 (2.2)
Staff courtesy	71 (1.9)
Phlebotomy services	58 (1.5)
Laboratory management responsiveness	34 (0.9)
Accessibility of laboratory manager	26 (0.7)
Courier services	22 (0.6)

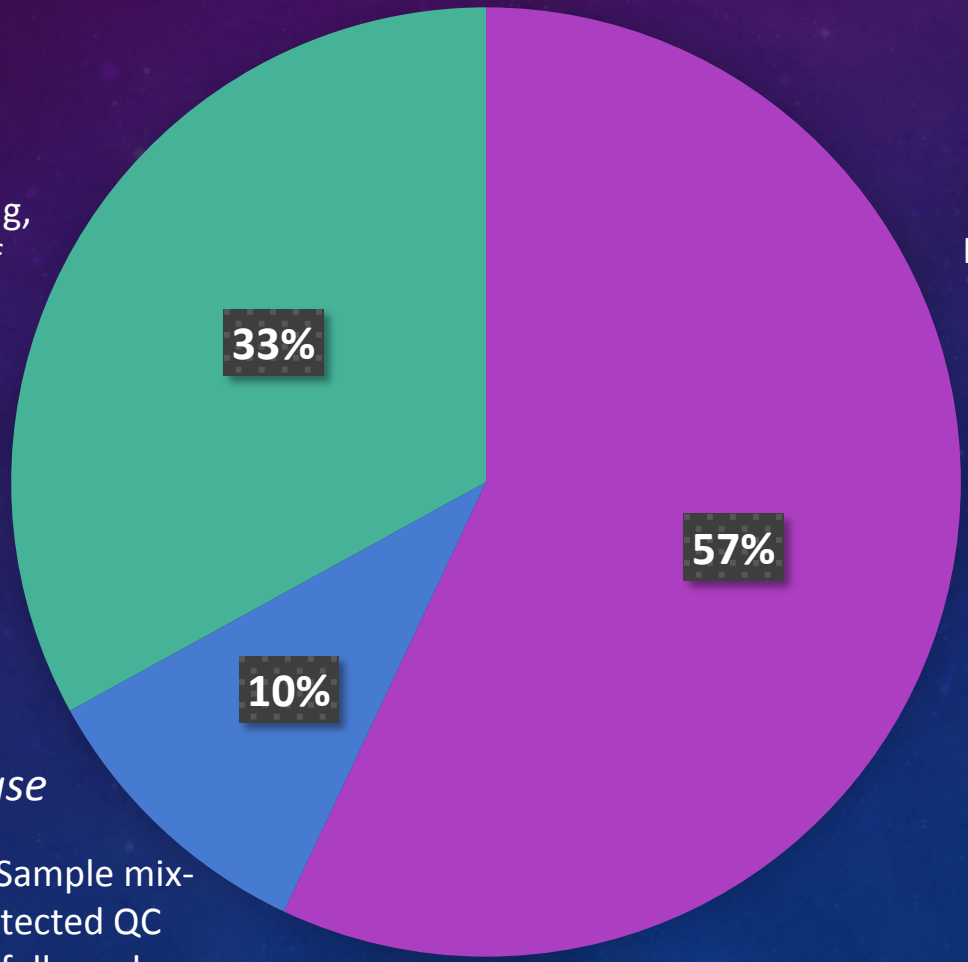
* TAT indicates turnaround time.

Bruce Jones, Leonas Bekeris, Raouf Nakhleh, Molly Walsh, Paul Valenstein (2009) Physician Satisfaction with Clinical Laboratory Services. Archives of Pathology & Laboratory Medicine: January 2009, Vol 133, pp38-43. http://www.archivesofpathology.org/doi/pdf/10.1043/1543-2165-133.1.38

ERRORS IN THREE MAIN PHASES

Post-Analytical Phase

Critical Value notification, failure in reporting, misinterpretation, erroneous validation of analytical data, clerical/reporting errors



Pre-Analytical Phase

Inappropriate test request, order entry error, misidentification of patient, inappropriate container, Blood to Anticoagulant ratio, labeling error, Hemolysis, QNS, Collection/Transport/Storage

Analytical Phase

Equipment malfunction, Sample mix-ups/interference, undetected QC failure, procedure not followed, Instrument capability (bias, precision)

*Julie Hammerling, A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today, LabMed February 2012 vol. 43 no.2 41-44 http://labmed.ascpjournals.org/content/43/2/41/T1.expansion.html

WHAT FACTORS CONTRIBUTE TO QUALITY?

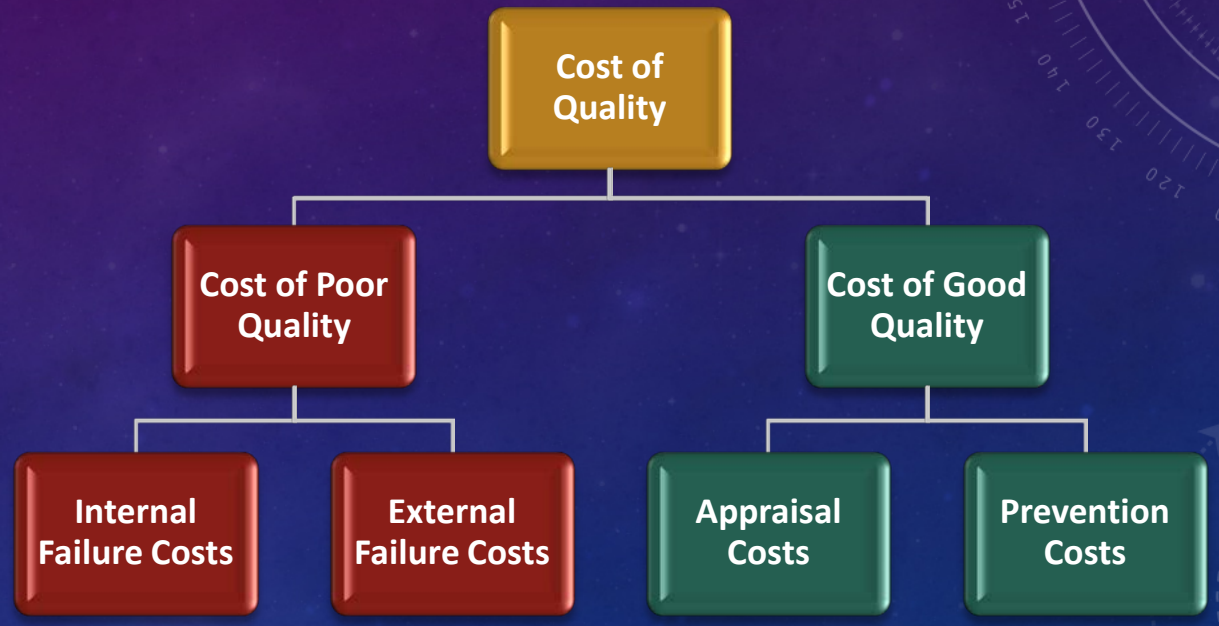
Parts Per Million for Published Q-Probes Laboratory Quality Indicators		
Quality Indicator	**DPMO**	**Sigma**
Six Sigma Quality	3.4	6
Pre-Analytic		
Chemistry Specimen Acceptability	3000	4.3
Hematology Specimen Acceptability	3800	4.2
Wristband errors	6500	4
Duplicate test orders	15200	3.7
Order Accuracy	18000	3.6
Surgical pathology specimen accessioning	34000	3.4
Cervicovaginal cytology specimen adequacy	73200	3
Therapeutic drug monitoring timing	244000	2.2
Analytic		
Laboratory proficiency testing	9000	3.9
Surgical pathology frozen section discordant diagnosis rate	17000	3.7
Papanicolaou smear rescreening false-negative rate	24000	3.5
Post-Analytic		
Reporting error	477	4.9

*David Nevalainen, Lucia Berte, Cheryl Kraft, Elizabeth Leigh, Lisa Picaso, and Timothy Morgan (*2000*) Evaluating Laboratory Performance on Quality Indicators With the Six Sigma Scale. Archives of Pathology & Laboratory Medicine: April 2000, Vol. 124, No. 4, pp. 516-519. http://www.archivesofpathology.org/doi/pdf/10.1043/0003-9985(2000)124%3C0516%3AELPOQI%3E2.0.CO%3B2

THE PRICE TAG OF QUALITY

Quality (good or poor) will always cost something. Proactive vs. Reactive actions will determine the

MAGNITUDE.

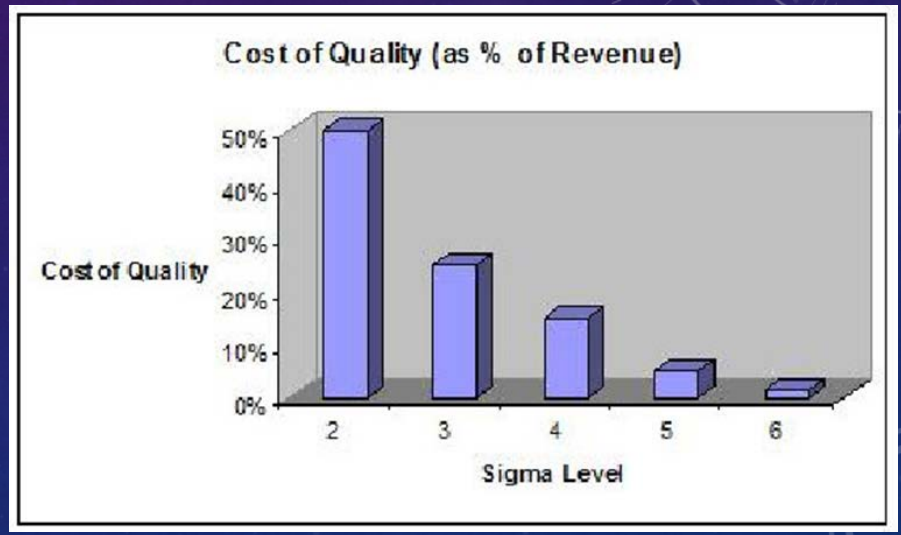


Arne Buthmann, Cost of Quality: Not only Failure Costs (2010). iSixSigma. http://www.isixsigma.com/implementation/financial-analysis/cost-quality-not-only-failure-costs/

THE PRICE TAG OF QUALITY

Sigma Level and the Cost of Quality		
Sigma Level	**DPMO**	**Cost of Quality as Percentage of Sales**
2	298,000	More than 40%
3	67,000	25-40%
4	6,000	15-25%
5	233	5-15%
6	3.4	Less than 1%

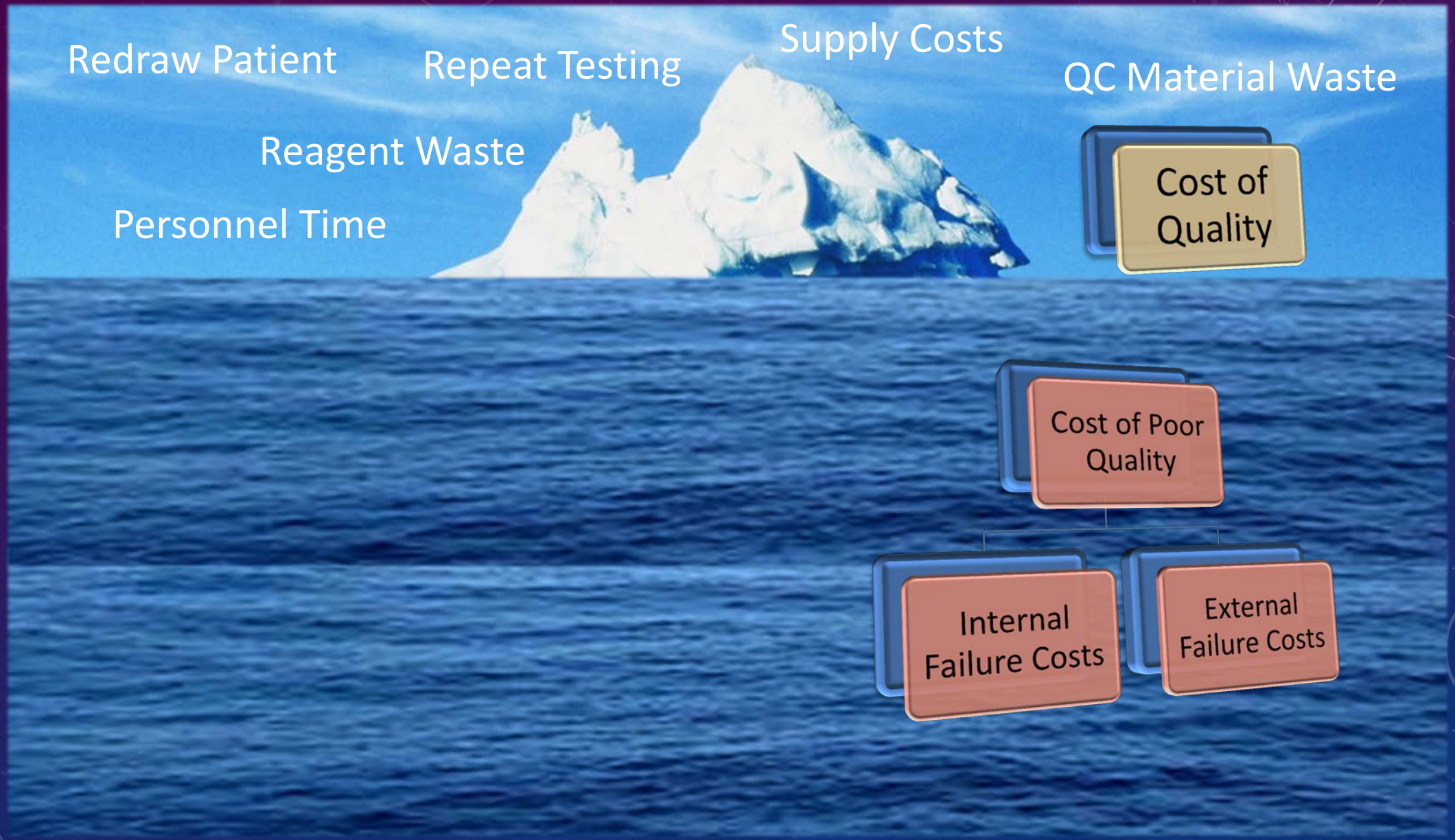
Arne Buthmann, Cost of Quality: Not only Failure Costs (2010). iSixSigma. http://www.isixsigma.com/implementation/financial-analysis/cost-quality-not-only-failure-costs/

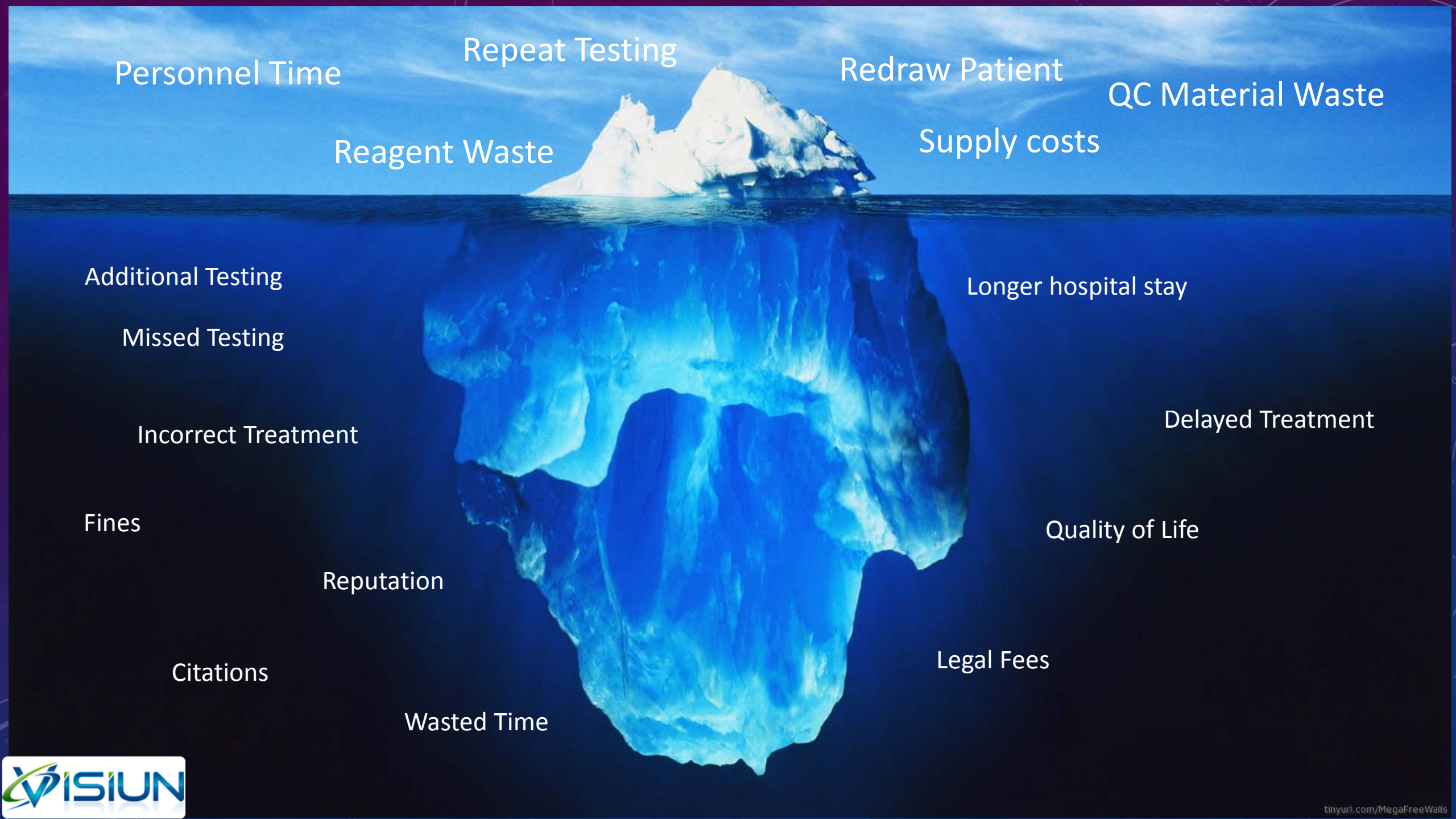


Paul Keller, Six Sigma Deployment, Does Six Sigma Work in Smaller Companies http://qualityamerica.com/Knowledgecenter/leansixsigma/does_six_sigma_work_in_smaller_companies

"The response to these issues is the realization the Six Sigma program will very quickly pay for itself."
- Paul Keller


Liquid QC, Proficiency Testing, Training, Maintenance, Supplies
Cost of Good Quality


Redraw Patient
Repeat Testing
Supply Costs
QC Material Waste
Reagent Waste
Personnel Time
Cost of Quality
Cost of Poor Quality
Internal Failure Costs
External Failure Costs


Personnel Time
Repeat Testing
Redraw Patient
QC Material Waste
Reagent Waste
Supply costs
Additional Testing
Longer hospital stay
Missed Testing
Incorrect Treatment
Delayed Treatment
Fines
Quality of Life
Reputation
Citations
Legal Fees
Wasted Time
VISIUN
tinyurl.com/MegaFreeWalls

60 – 80 % OF MEDICAL DECISIONS ARE BASED ON LAB RESULTS

HIGHLY PUBLICIZED LAB ERRORS

- Q Probes from 2011 - reference to 2001 St. Agnes PT/INR patient deaths
- Quest and Nichols Institute Diagnostics paid $302 Million over PTH test kits
- Baltimore, Maryland HIV/ Hepatitis equipment malfunctions 2002-2004

CAP TODAY

March 2011
Feature Story

Karen Lusky

A recent Q-Probes study, "Patient Safety Practices for Monitoring PT/INR,"
ing about the potential for dangerous lab errors and presents a case
g coagulation laboratory practices.
Agnes Hospital in Philadelphia

THE BALTIMORE SUN

Ill ex-hospital worker cites lab troubles, fearing worst

Inquiry: kristin s. turner, suing maryland general after contracting hiv, recalls faulty equipment and fears thousands of questionable tests.

By Walter F. Roche Jr.

Sun Staff

March 19, 2004

The woman who alerted health officials to questionable HIV laboratory tests at Maryland General Hospital - and is now infected with HIV herself - says she's convinced that problems at the health care facility are more serious and pervasive than inspectors have discovered.

Kristin S. Turner, a former lab worker at the hospital, said she fears there could have been thousands of questionable tests for HIV and hepatitis, instead of the hundreds officials have identified in an inspection of the 245-bed health care facility.

It was a complaint from Turner late last year that triggered the initial inquiry by the state Office of Health Care Quality.

In an interview at her attorney's office yesterday, Turner said her life has been irreversibly changed by contracting HIV and hepatitis - the result, she contends, of being showered with infected blood serum when the hospital's testing equipment malfunctioned.

"It was the worst nightmare of every medical worker," she said softly but firmly. "Everything about my life has changed. It tore it completely apart, turned it upside down."

Turner, 32, filed a lawsuit last week in Baltimore Circuit Court against Maryland General and Adaltis USA Inc., the manufacturer of the blood analyzer.

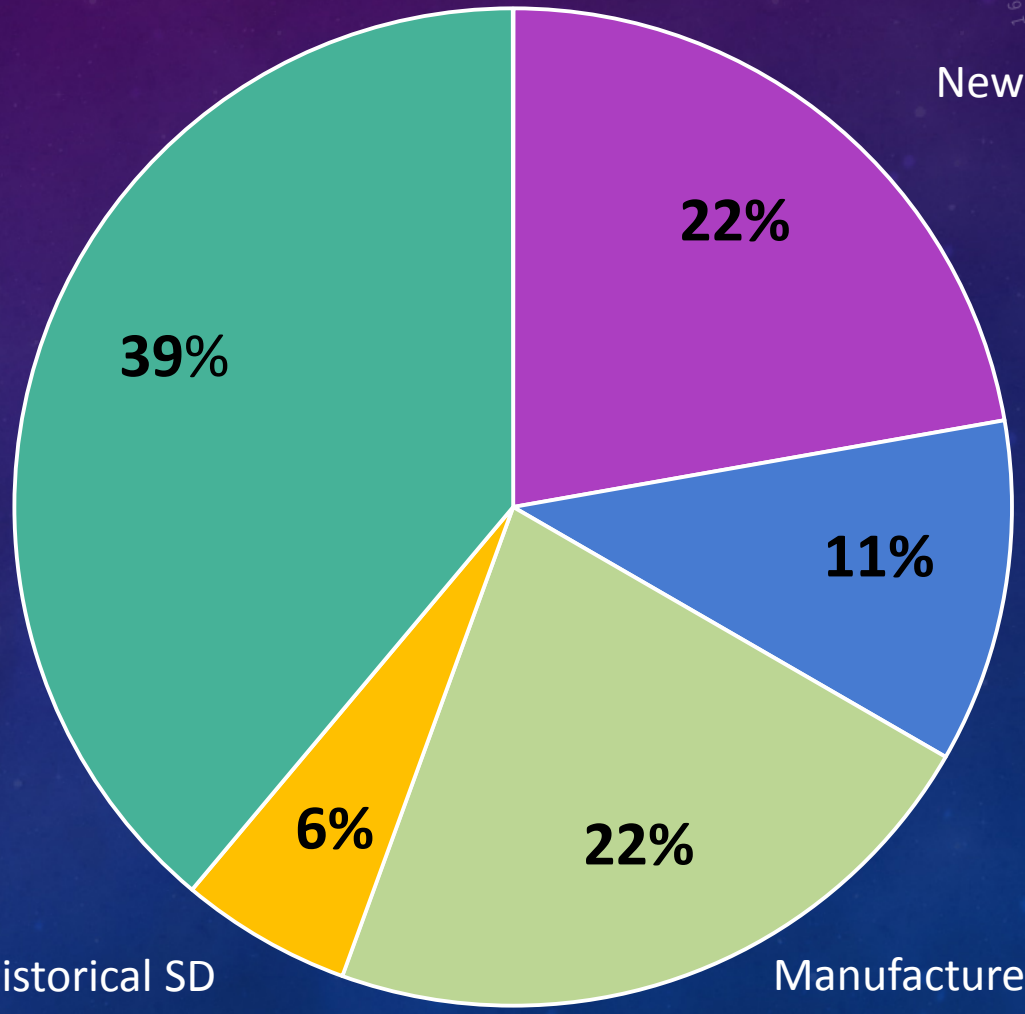
Hospital officials released a three-paragraph statement last night in which they announced hiring PCS Laboratory Solutions of Midway, Utah, to provide immediate lab management support, perform a comprehensive review of the hospital's lab and make any changes. Officials also stated that they would expand efforts to "contact everyone who should be retested." Lee Kennedy, a

HOW DO WE
KEEP THIS FROM HAPPENING
IN OUR LABS!?

WHAT DO WE CURRENTLY DO?

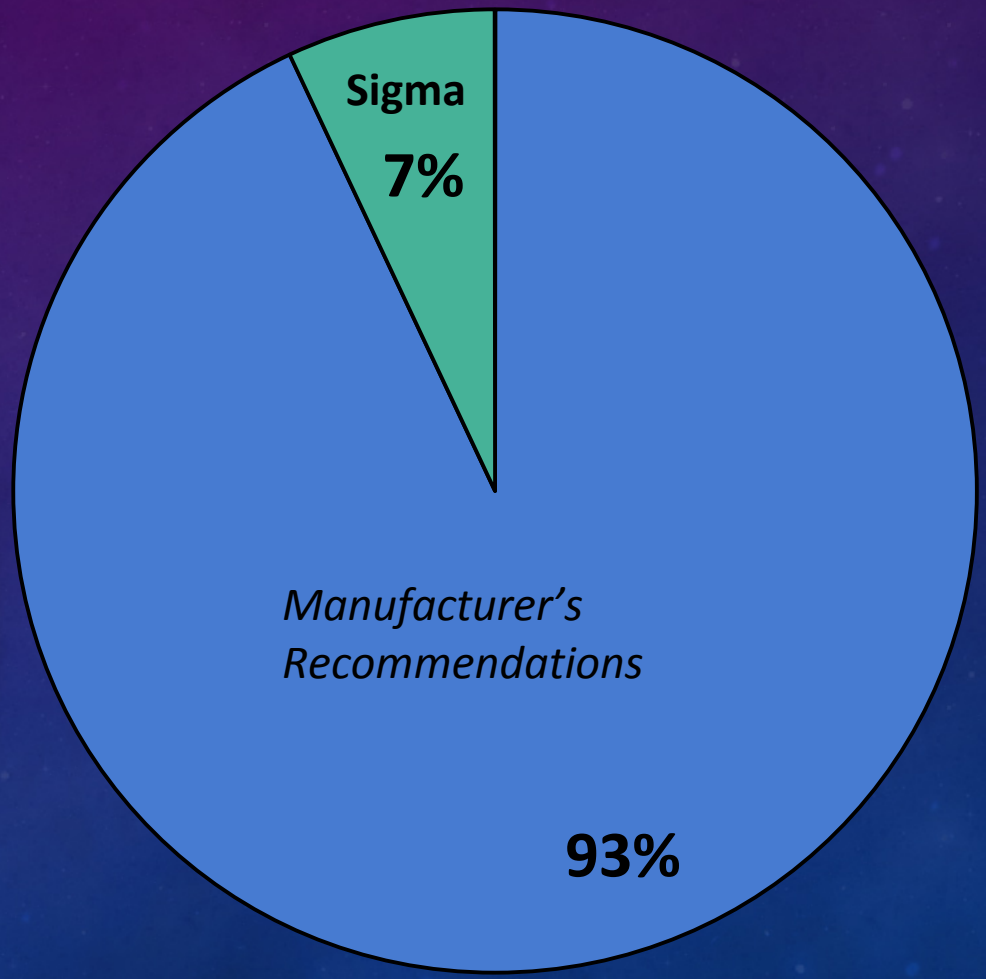
- Daily Quality Control
- Proficiency Testing
- Periodic QC submission to peer review group

HOW DO YOU SELECT YOUR QC RANGES?



HOW DO YOU DECIDE NUMBER AND FREQUENCY OF QC?

Is there a right way?



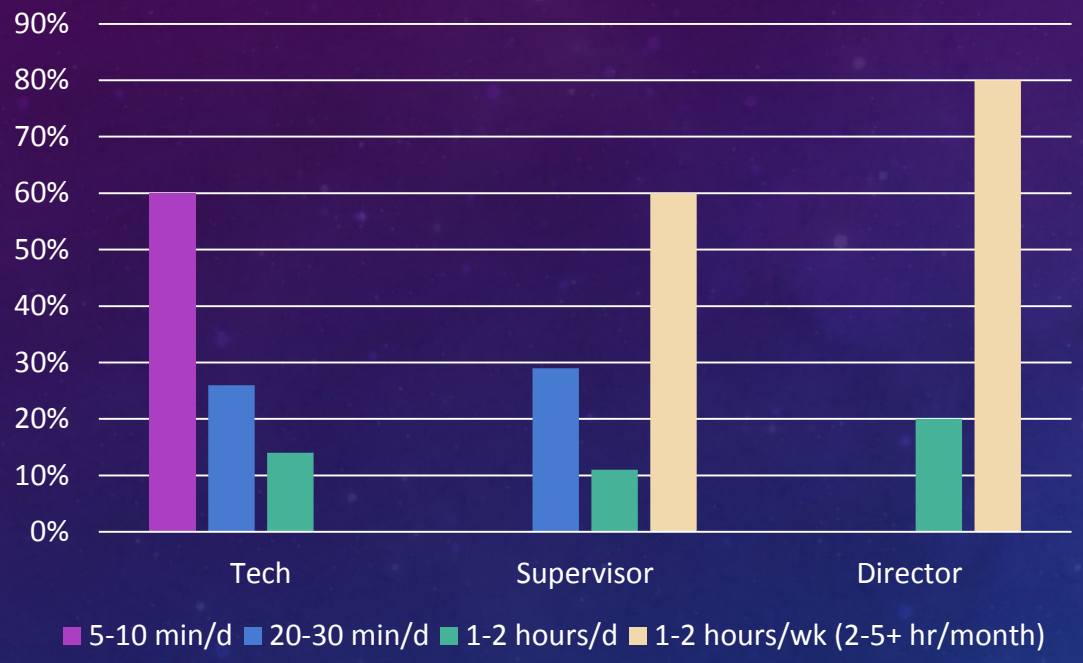
WHAT DO THE NUMBERS SAY?

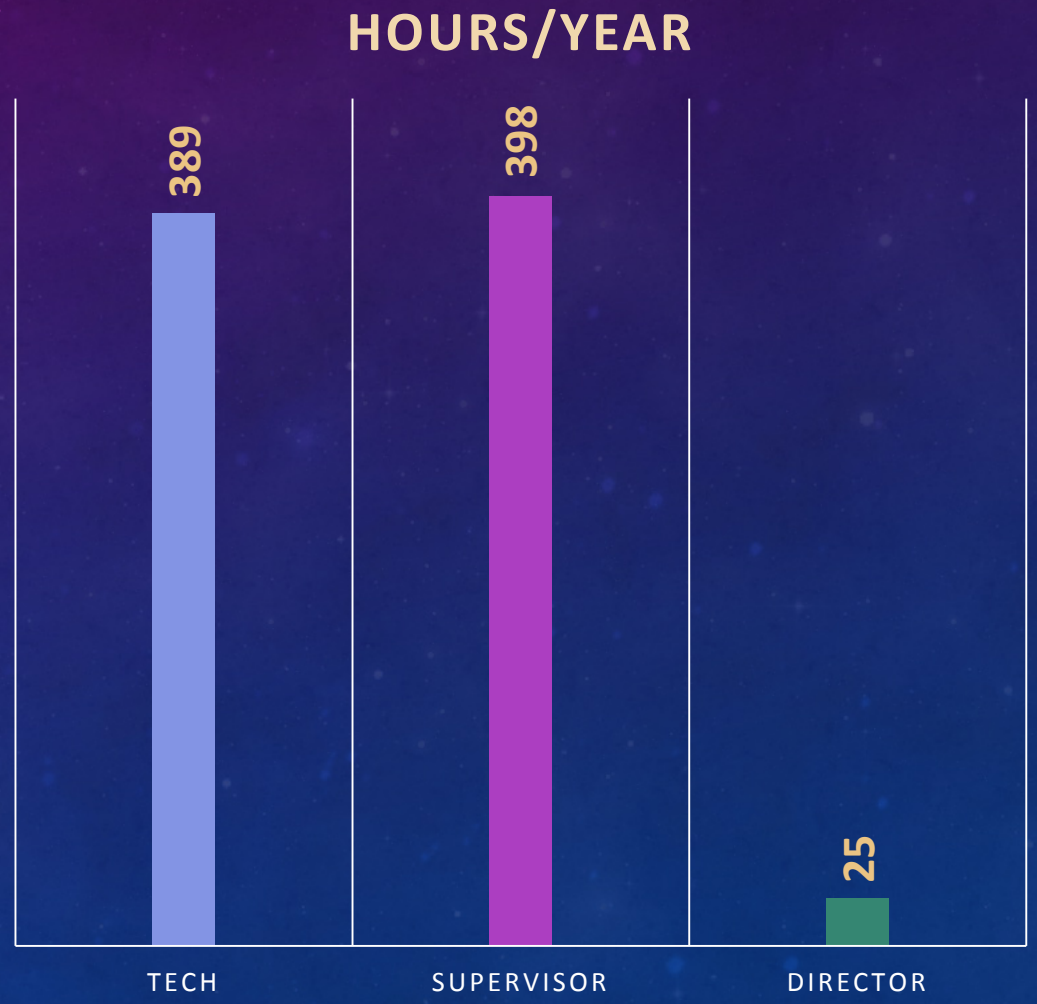
Runs/day	Runs/year	Probability of False Rejection	Unnecessary runs/year	Cost/run	1 method	5 methods	20 methods
A. Cost of repeating run of 20 specimens and 2 controls when cost of each is $0.50							
1	365	0.09	33	$11.00	$361.35	$1,806.75	$7,227.00
2	730	0.09	66	$11.00	$722.70	$3,613.50	$14,454.00
3	1095	0.09	99	$11.00	$1,084.05	$5,420.25	$21,681.00
4	1460	0.09	131	$11.00	$1,445.40	$7,227.00	$28,908.00
B. Cost of repeating run of 20 specimens and 3 controls when cost of each is $0.50							
1	365	0.14	51	$11.50	$587.65	$2,938.25	$11,753.00
2	730	0.14	102	$11.50	$1,175.30	$5,876.50	$23,506.00
3	1095	0.14	153	$11.50	$1,762.95	$8,814.75	$35,259.00
4	1460	0.14	204	$11.50	$2,350.60	$11,753.00	$47,012.00

*James Westgard. Westgard QC. 2009. $aving the Cost$ of Poor Quality. http://www.westgard.com/essay42.htm#1

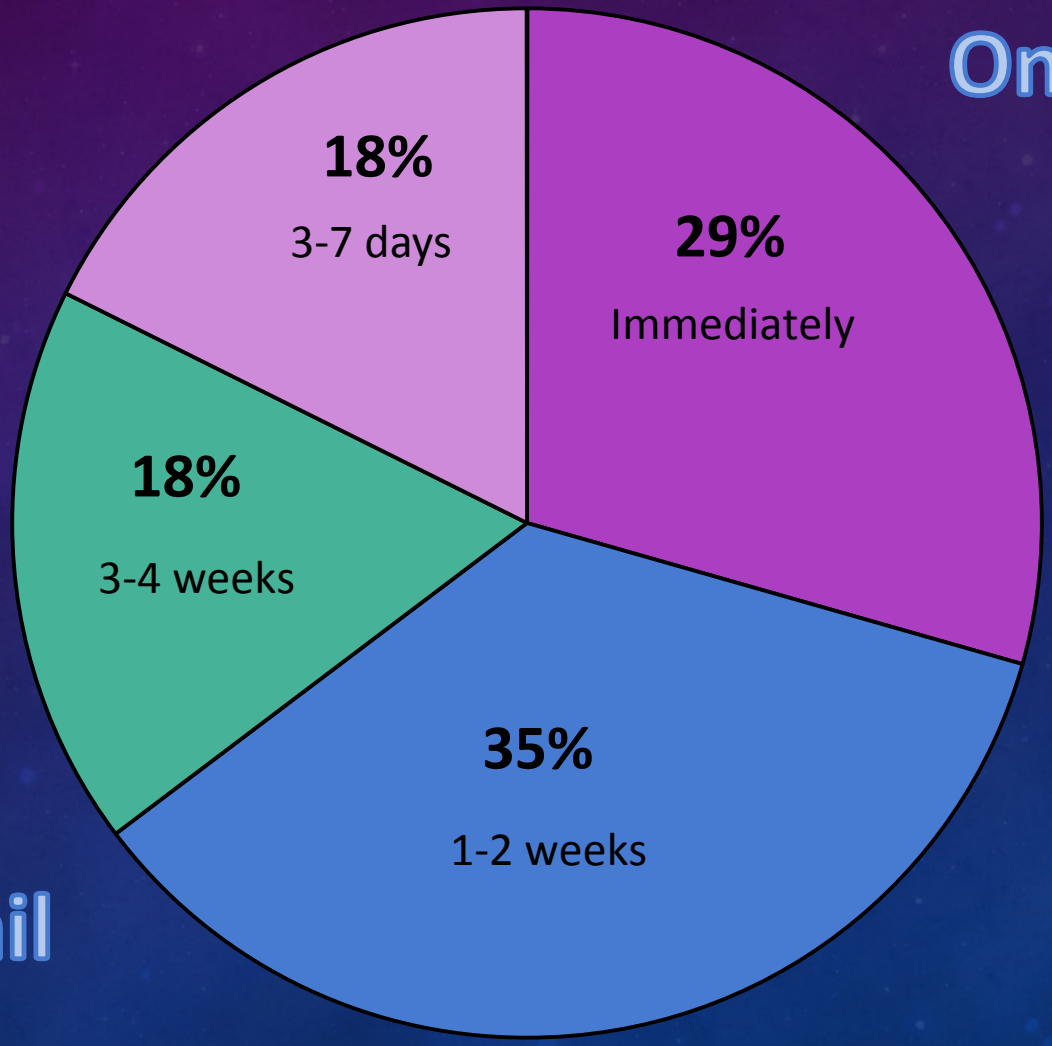
VISIUN

HOW MUCH TIME DO YOU SPEND REVIEWING QC DATA?





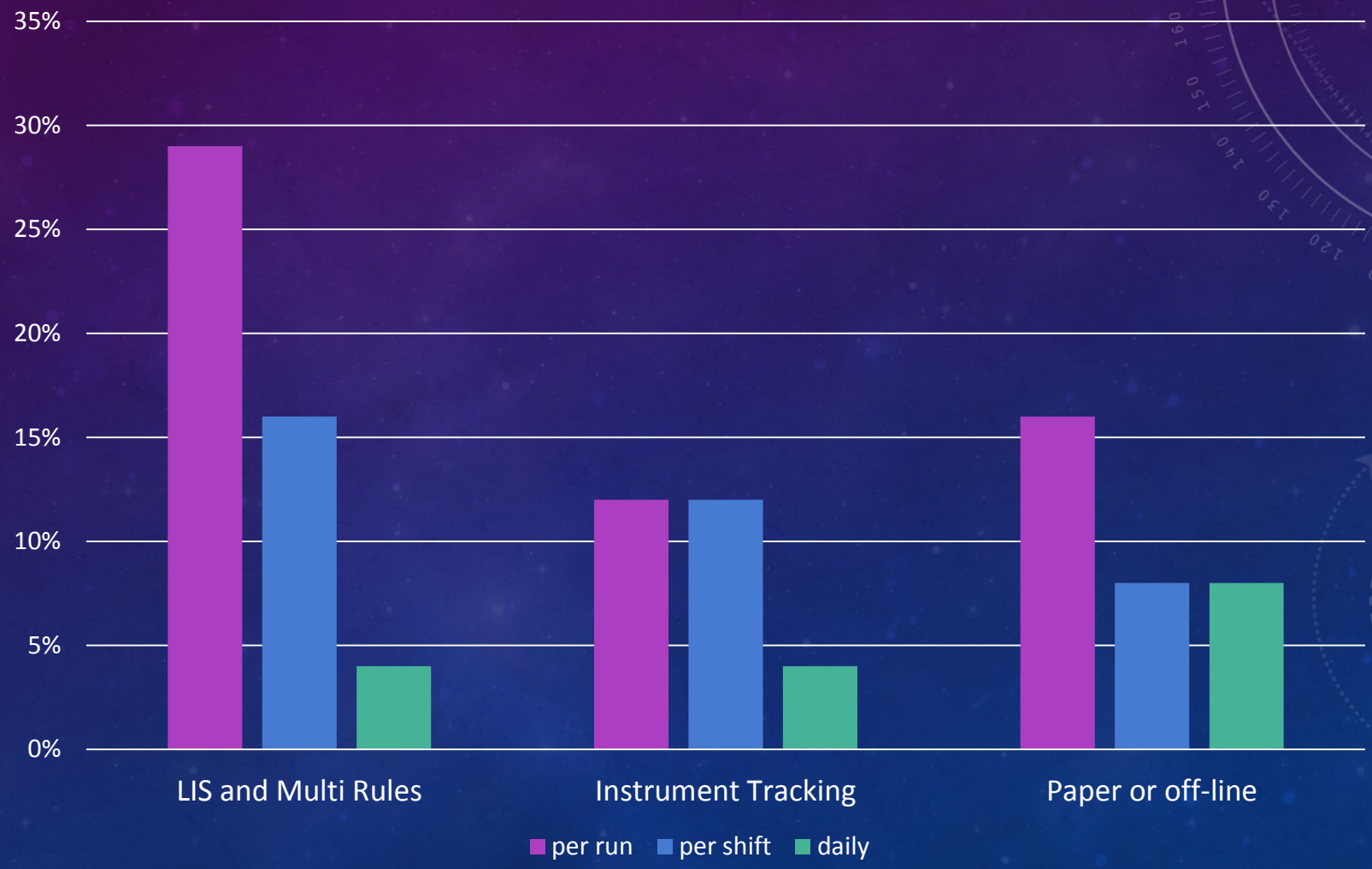
WAITING FOR PEER GROUP QUALITY CONTROL DATA



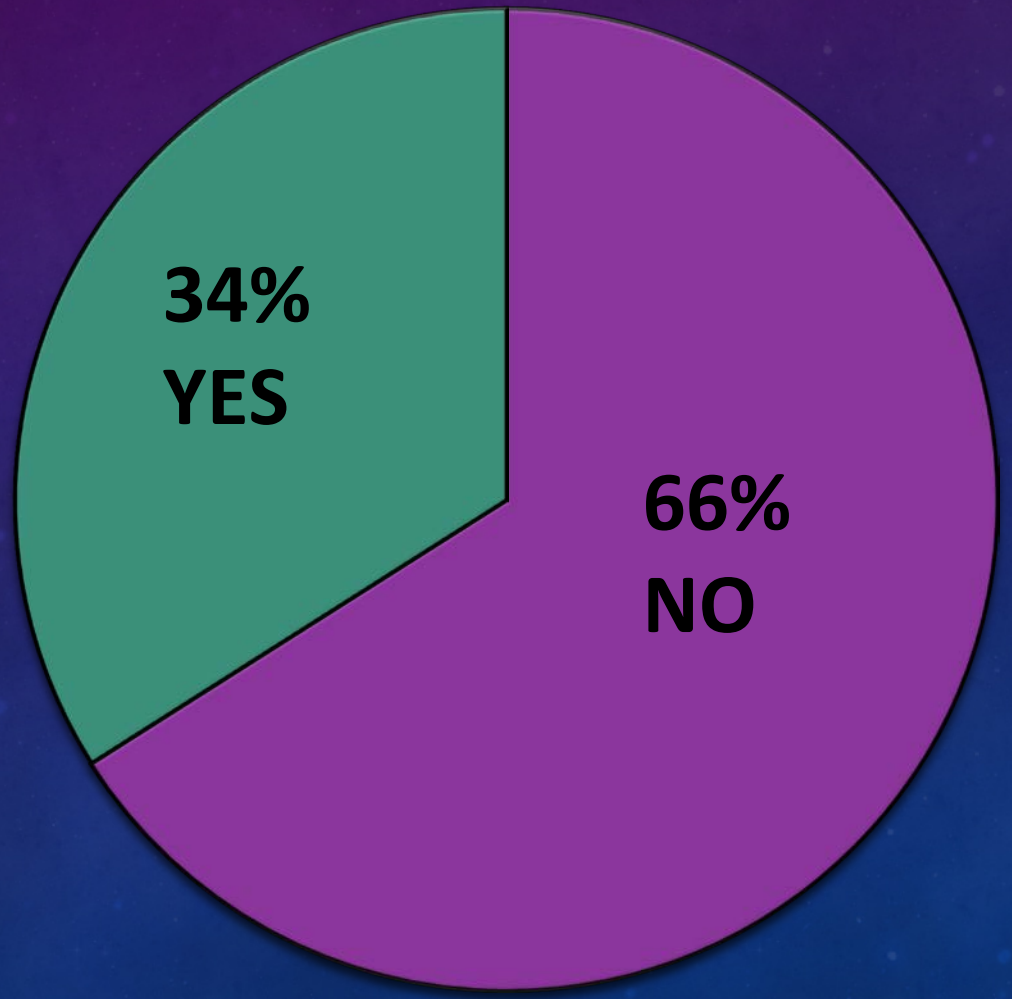
HOW DO YOU MONITOR YOUR QC DATA?

A VARIETY OF QC APPROACHES

None responded that they could compare multiple analyzers within their institution

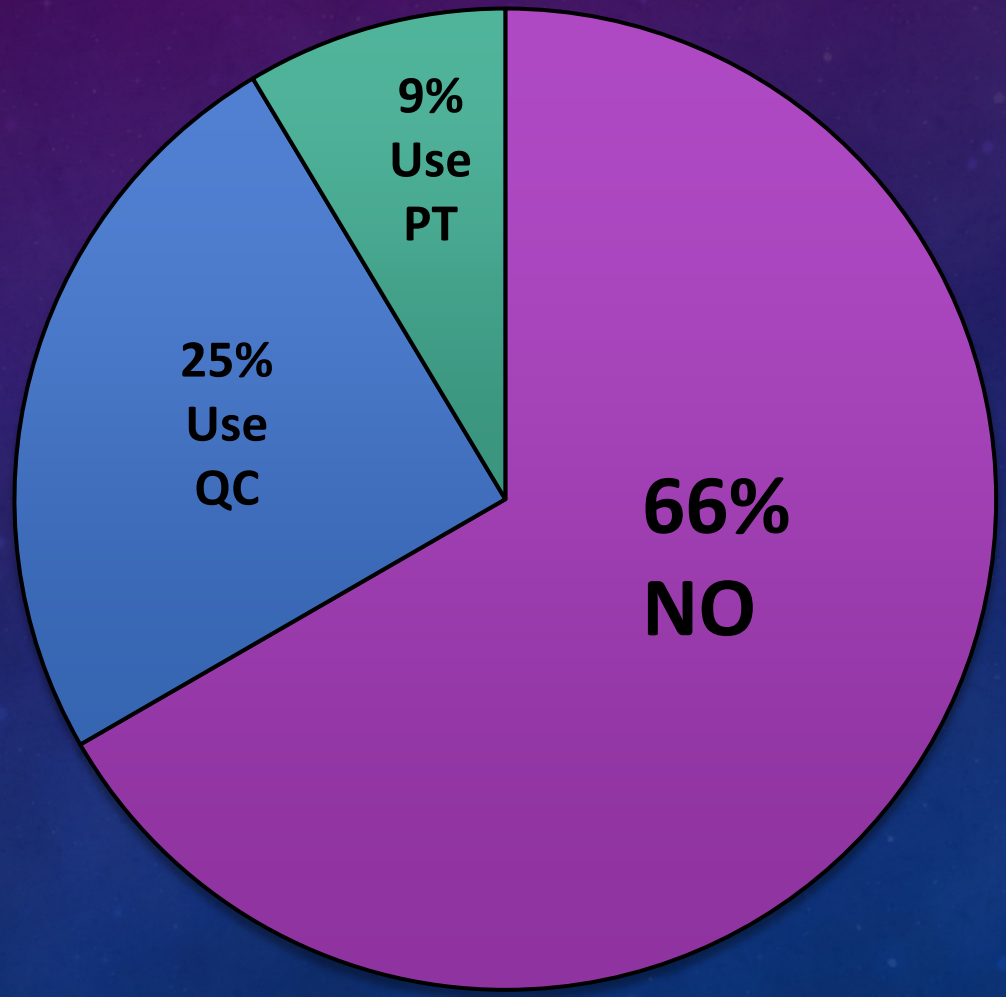


DO YOU USE SIGMA METRICS IN YOUR QC PLAN?



DO YOU USE SIGMA METRICS IN YOUR QC PLAN?

IF YES, HOW DO YOU CALCULATE THE BIAS?



ENTER EP23 AND THE INDIVIDUALIZED QUALITY CONTROL PLAN

"An effective QCP will optimize the probability of detecting an error while minimizing the probability of false error detection." – EP23AE

THREE BASIC STEPS TO CONSTRUCT AND EXECUTE YOUR IQCP

1. Perform a risk analysis – Identify all areas of potential weakness/error
2. Define measures to diminish the occurrence of such errors
3. Monitor the process continually to ensure quality and modify if necessary

1. PERFORM A RISK ANALYSIS – IDENTIFY ALL AREAS OF POTENTIAL WEAKNESS/ERROR

Phase	Potential Errors
Pre-Analytical	Inappropriate test request, order entry error, misidentification of patient, inappropriate container, Blood to Anticoagulant ratio, labeling error, Hemolysis, QNS, Collection/Transport/Storage
Analytical	Equipment malfunction, Sample mix-ups/interference, undetected QC failure, procedure not followed, Instrument capability
Post-Analytical	Critical Value notification, failure in reporting, erroneous validation of analytical data, clerical/reporting errors

1. PERFORM A RISK ANALYSIS – IDENTIFY ALL AREAS OF POTENTIAL WEAKNESS/ERROR

Table 1. Sources for Collecting Information for Risk Analysis

Information	Source
Regulatory and accreditation requirements • Mandated QC procedures • Required quality assurance activities • Regulatory agency recall and device failure notifications	Regulatory authorities; accreditation agencies
Measuring system information • Intended use (including limitations, warnings, and precautions) • Environmental requirements • Instructions for calibration, maintenance, use, and reagent storage • Calibrator traceability information • QC features • Risk mitigation recommendations	*In vitro* diagnostic (IVD) manufacturer
Laboratory information • Environmental conditions, including facilities and utilities, and existing controls • Installation/operational qualification reports • Operator training and competency • Internal performance evaluation/verification data • External performance data (eg, proficiency test results) • Process map covering the steps analyzed	Laboratory
Publications and reports from laboratory peers • Published performance evaluations • Published clinical studies • Other users (eg, user groups, listservs, forums)	Laboratory
Clinical information • Clinical applications for use of a test result • Biological reference intervals and clinical decision levels • Foreseeable medical errors that could result from incorrect, delayed, or no results • The severity of patient harm that would result from the hazardous situations	Laboratory, in consultation with medical users of the test results

*CLSI EP23-A p.21 Section 6.1

1. PERFORM A RISK ANALYSIS – IDENTIFY ALL AREAS OF POTENTIAL WEAKNESS/ERROR

Analytical Sigma Analysis

Table 1. Sources for Collecting Information for Risk Analysis

Information	Source
Regulatory and accreditation requirements • Mandated QC procedures • Required quality assurance activities • Regulatory agency recall and device failure notifications	Regulatory authorities; accreditation agencies
Measuring system information • Intended use (including limitations, warnings, and precautions) • Environmental requirements • Instructions for calibration, maintenance, use, and reagent storage • Calibrator traceability information • QC features • Risk mitigation recommendations	*In vitro* diagnostic (IVD) manufacturer
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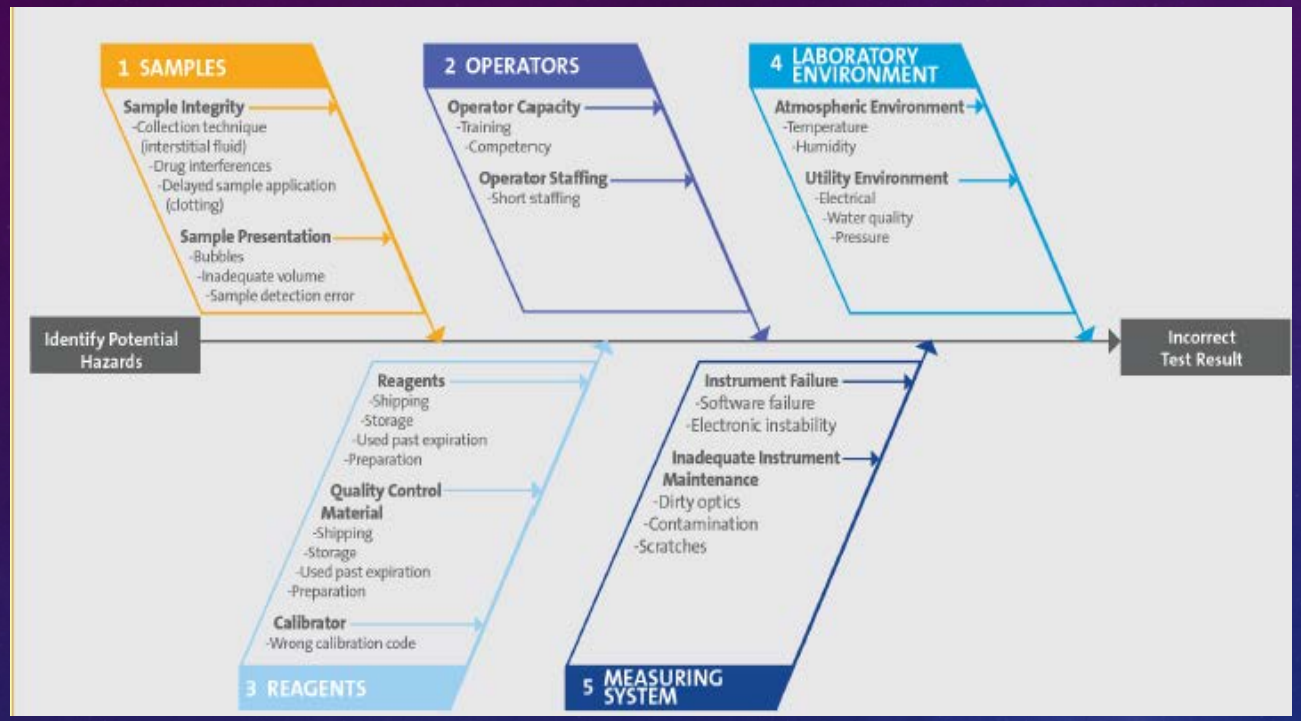
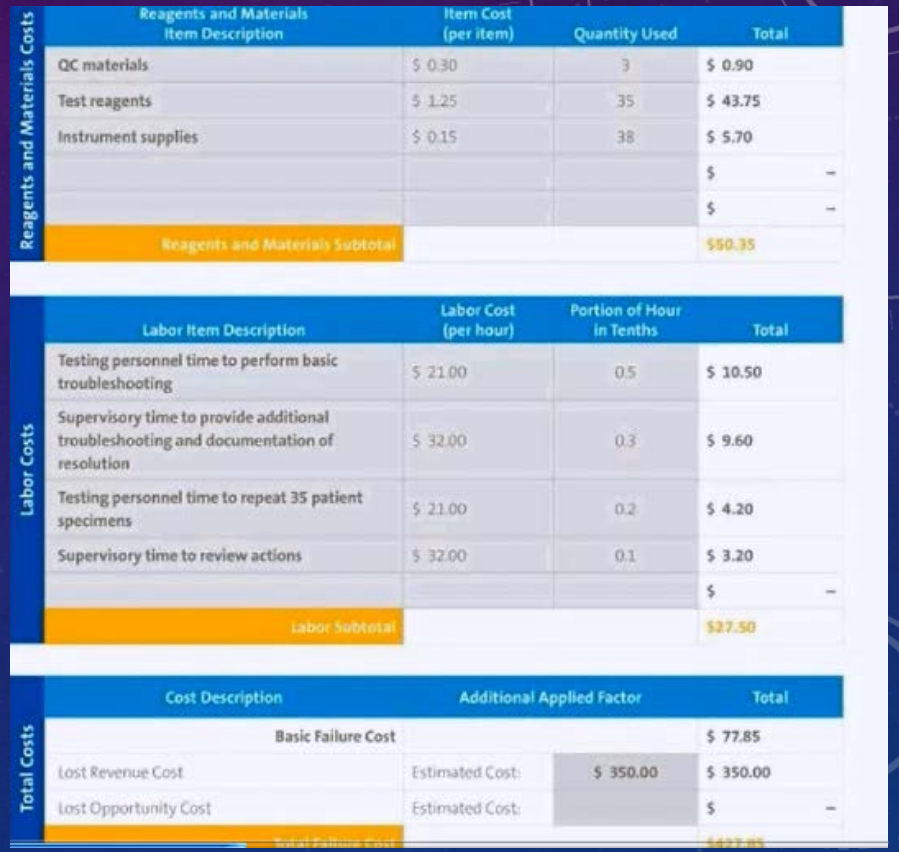
*CLSI EP23-A p.21 Section 6.1

HELPFUL RESOURCES FROM CLSI – EP23 AND QMS20-R





Reagents and Materials Costs

Reagents and Materials Item Description	Item Cost (per item)	Quantity Used	Total
QC materials	$ 0.30	3	$ 0.90
Test reagents	$ 1.25	35	$ 43.75
Instrument supplies	$ 0.15	38	$ 5.70
			$ –
			$ –
Reagents and Materials Subtotal			$50.35

Labor Costs

Labor Item Description	Labor Cost (per hour)	Portion of Hour in Tenths	Total
Testing personnel time to perform basic troubleshooting	$ 21.00	0.5	$ 10.50
Supervisory time to provide additional troubleshooting and documentation of resolution	$ 32.00	0.3	$ 9.60
Testing personnel time to repeat 35 patient specimens	$ 21.00	0.2	$ 4.20
Supervisory time to review actions	$ 32.00	0.1	$ 3.20
			$ –
Labor Subtotal			$27.50

Total Costs

Cost Description	Additional Applied Factor		Total
Basic Failure Cost			$ 77.85
Lost Revenue Cost	Estimated Cost:	$ 350.00	$ 350.00
Lost Opportunity Cost	Estimated Cost:		$ –

	Severity of Harm				
Probability of Harm	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	unacceptable	unacceptable	unacceptable	unacceptable	unacceptable
Probable	acceptable	unacceptable	unacceptable	unacceptable	unacceptable
Occasional	acceptable	acceptable	acceptable	unacceptable	unacceptable
Remote	acceptable	acceptable	acceptable	unacceptable	unacceptable
Improbable	acceptable	acceptable	acceptable	acceptable	acceptable

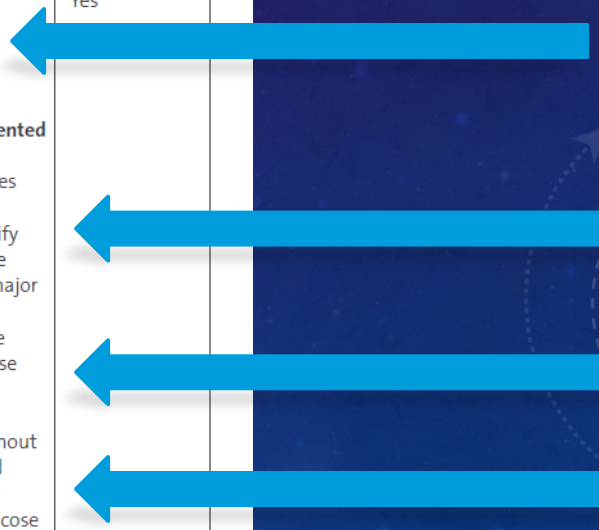
2. DEFINE MEASURES TO DIMINISH THE OCCURRENCE OF SUCH ERRORS

Phase	Potential Errors	Steps in Place to Detect Errors	
Pre-Analytical	Inappropriate test request, order entry error, misidentification of patient, inappropriate container, Blood to Anticoagulant ratio, labeling error, Hemolysis, QNS, Collection/Transport/Storage	Observation/Documentation, Procedure Modification, Delta Checks	
Analytical	Equipment malfunction, Sample mix-ups/interference, undetected QC failure, procedure not followed, Instrument capability	Alter Quality Control processes, Change methods	
Post-Analytical	Critical Value notification, failure in reporting, erroneous validation of analytical data, clerical/reporting errors	Procedure Modification, Documentation	

2. DEFINE MEASURES TO DIMINISH THE OCCURRENCE OF SUCH ERRORS

An Illustrative Example of a Glucose Measurement on an Automated Measuring System

Row #	Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)
6	Incorrect results due to sample carryover	Use disposable cuvettes and wash mechanism for probes. The wash mechanism removes residual glucose left over from a high-concentration sample.	Inadequate washing following a high glucose concentration sample can cause false elevations in the subsequent sample.	Partial – requires additional laboratory mitigations.	**Manufacturer recommendations:** – Perform routine maintenance. **Laboratory-implemented control processes:** – Analyze QC samples before and after maintenance to verify system performance before and after a major system change. – Repeat any sample that follows a glucose >480 mg/dL (26.7 mmol/L). – Report results without autoverification and use the LIS to notify operator of high glucose specimens.	Yes



*CLSI EP23-A Appendix C p.76

3. MONITOR THE PROCESS CONTINUALLY TO ENSURE QUALITY AND MODIFY IF NECESSARY

CLIA UPDATE – December 2013
Division of Laboratory Services
Centers for Medicare and Medicaid Services
Top 10 Deficiencies in the Nation – CMS Surveys

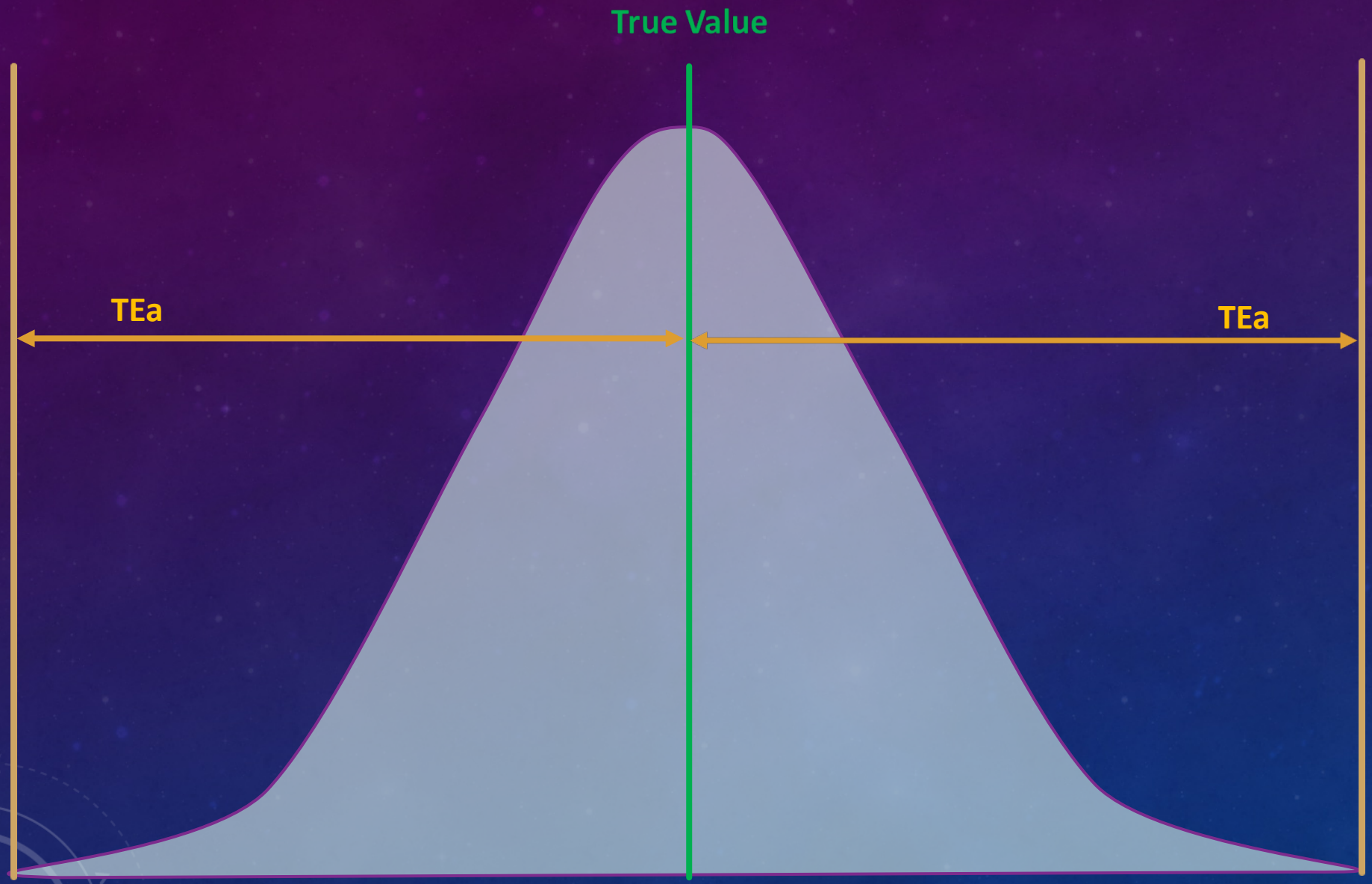
Regulatory Subpart	Regulatory Cite	Deficiency	# all labs with deficiency	% all labs with deficiency	# POLs with deficiency	% POLs with deficiency
Analytic Systems (D5413) STANDARD	493.1252(b)	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented.	973	5.44%	661	5.65%
Analytic Systems (D5791) STANDARD	493.1289(a)	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.	832	4.66%	285	2.44%

*CLIA Update December 2013 , CLIA Top Ten Deficiencies in the Nation, pg. 1.
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf

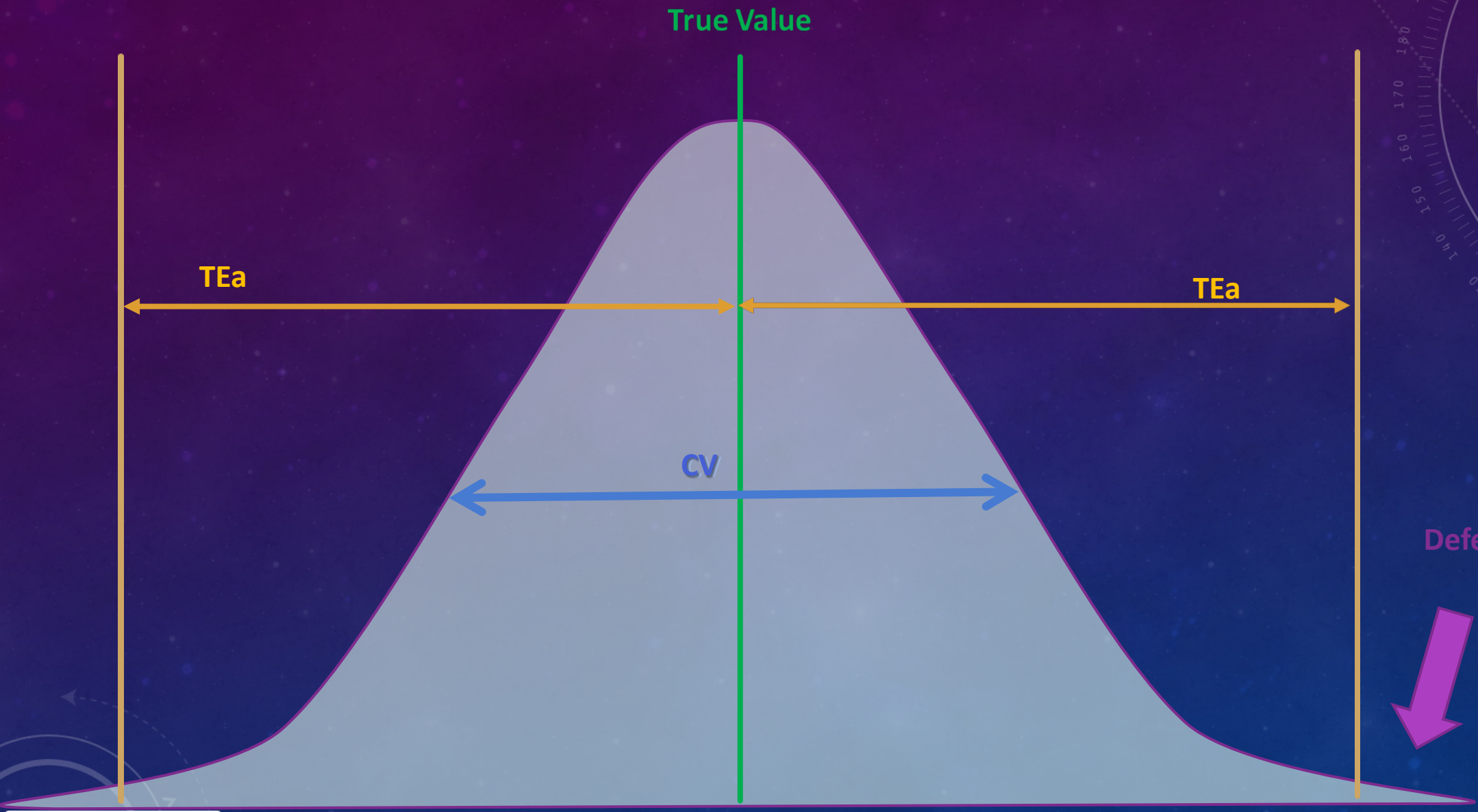
HOW PERFORMANCE INSIGHT™ REPORTS RELATE TO VARIOUS PHASES IN THE PROCESS

Phase	Potential Errors	Reports to Monitor Error Rates
Pre-Analytical	Hemolysis, QNS, Transport/Storage	
Analytical	Instrument capability, Instrument error	
Post-Analytical	Critical Value notification, clerical/reporting errors	

IDEAL TEST CONDITIONS

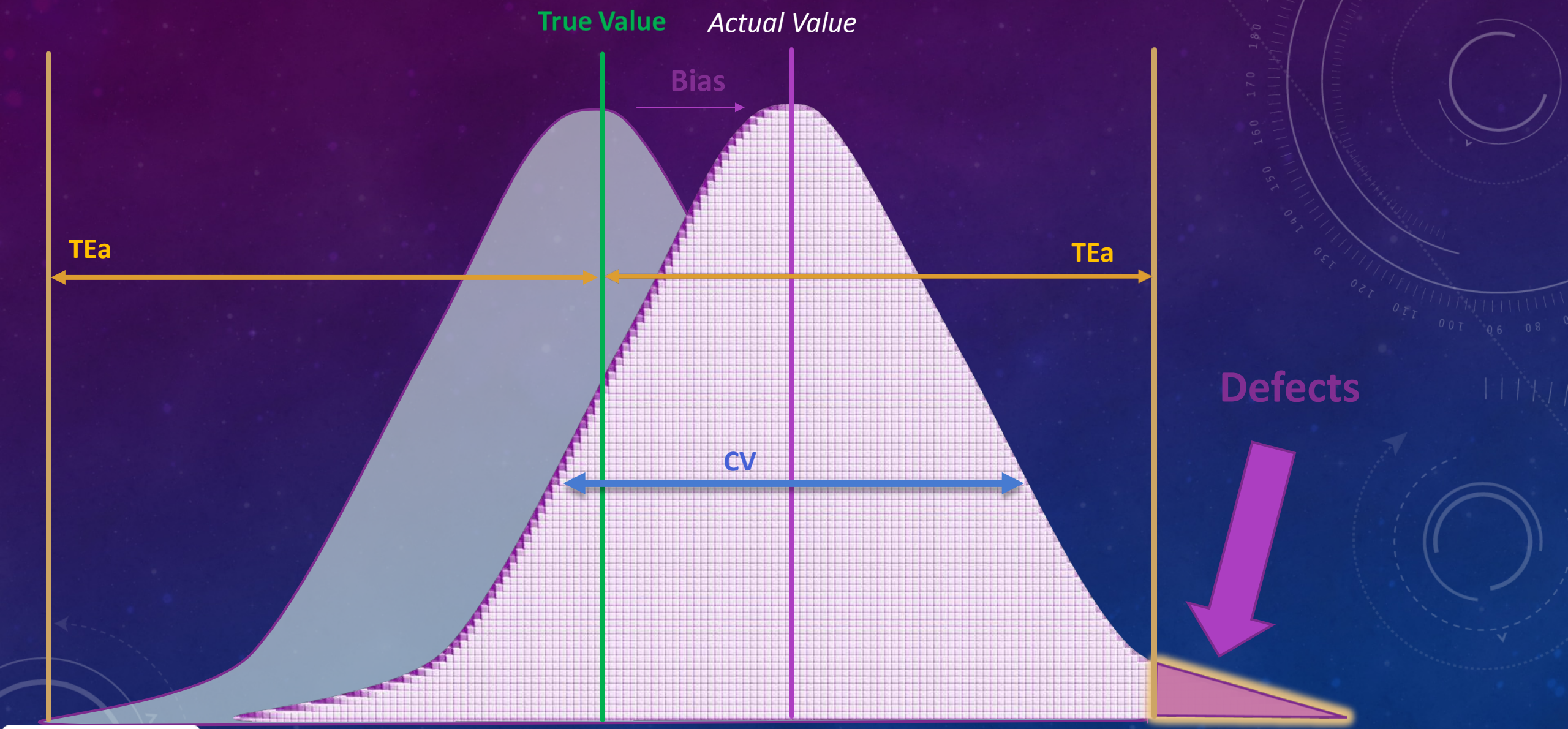


INCREASED CV



SIGMA METRICS

SIGMA = (TEa – Bias) /SD



THE 'PRICE TAG' OF QUALITY

Table1: Sigma scores calculated during validation of the Cobas 6000, at 2 concentration levels.

mat	Analyte	level 1	VC 1	Sigma1	level 2	VC 2	Sigma2
S	CRP	10.2	2.9	19.6	44.3	1.6	36.1
S	Lipase	32	1.6	18.6	65	0.9	31.5
S	Triglycerides.	1.13	2.3	12.1	2.04	1.3	21.1
S	ALAT	55	1.5	22.1	168	1.5	20.7
S	ASAT	81	2.5	6.2	293	0.8	19.4
S	Bilirubine conj.	19.1	4.5	9.9	63.1	2.5	17.7
S	CK						
S	Iror						
S	Am						
S	Bili						
S	Uri						
S	Ure						
S	LDI						
S	Ch						
S	Alk						
S	Ph						
S	Glu						
S	Pot						
S	Ma						
S	Alb						
S	Pro						
S	HD						
S	Cre						
S	Cal						
S	Tra						
S	Chl						
S	Soc						

Sigma score	Westgard rules	P_{fr}	P_{ed}	N	R
3.0	$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	0.02	0.36	4	1
3.2	$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	0.03	0.48	4	1
3.4	$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	0.03	0.65	4	1
3.6	$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	0.03	0.79	4	1
3.8	$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	0.03	0.86	4	1
4.0	$1_{3s}/2_{2s}/R_{4s}/4_{1s}$	0.03	0.91	4	1
4.2	$1_{2.5s}$	0.04	0.92	4	1
4.4	$1_{2.5s}$	0.04	0.96	4	1
4.6	1_{3s}	0.01	0.92	4	1
4.8	$1_{2.5s}$	0.03	0.93	2	1
5.0	$1_{2.5s}$	0.03	0.96	2	1
5.2	1_{3s}	0.00	0.91	2	1
5.4	1_{3s}	0.00	0.94	2	1
5.6	1_{3s}	0.00	0.97	2	1
5.8	$1_{3.5s}$	0.00	>0.89	2	1
6.0	$1_{3.5s}$	0.01	>0.89	2	1

In a period of 4 years we realised a reduction of 75% in the consumption of our multicontrol materials on the analyzers.

This resulted in a saving of over € 21000 on an annual basis.
Furthermore there is a reduction in consumption of calibrator material and reagents caused by the reduced number of reruns and calibrations and unnecessary replacement of reagent cassettes.

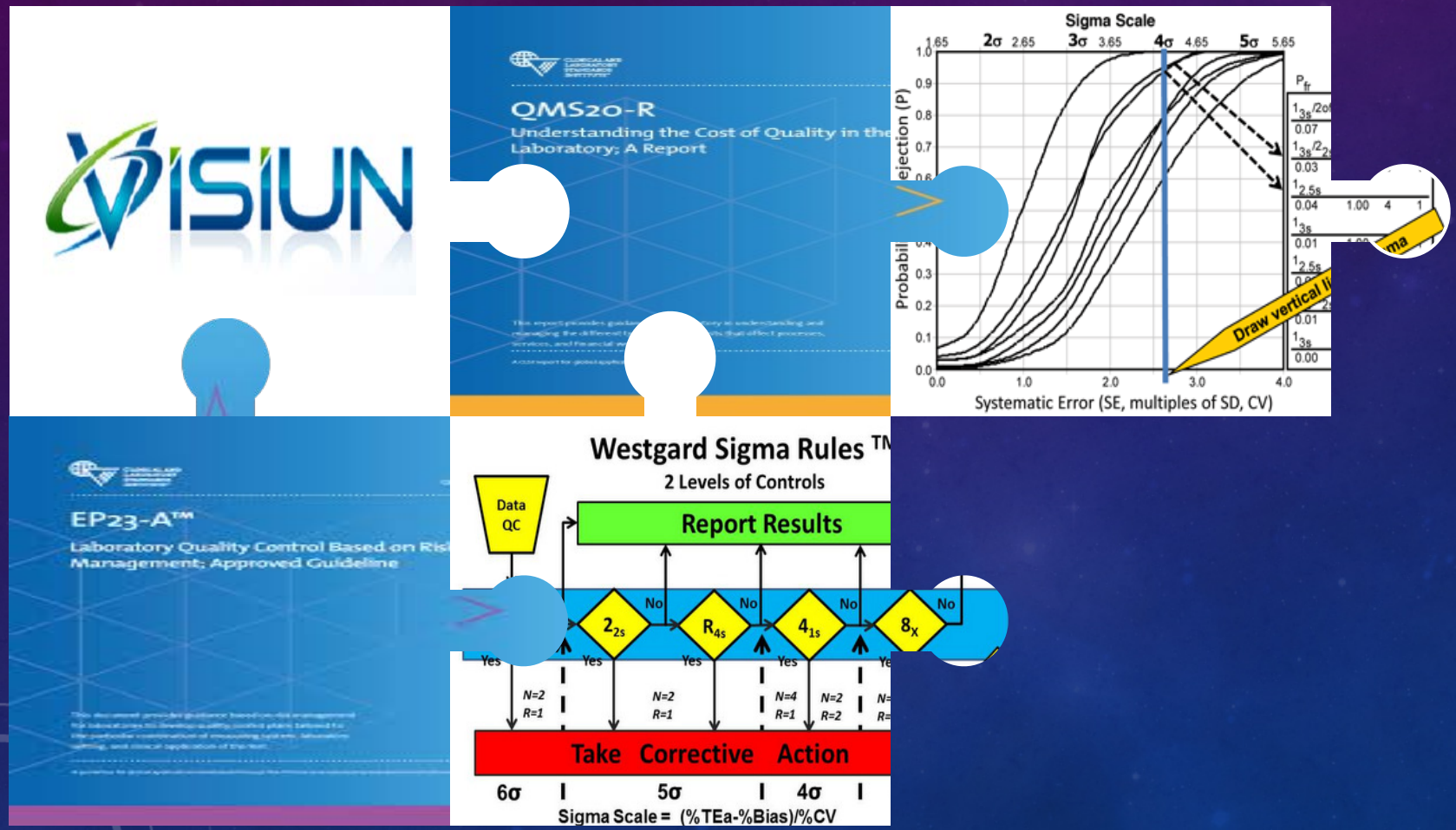
Beside the reduction in “costs of material” we also realised lowered “costs of failures” in terms of avoiding time spent by the technician solving “false” IQC-alarms. As a result of IQC design less stringent IQC rules were applied in many of the analytical test procedures leading to less alarms, strongly reduced number of reruns, calibration runs and technical interventions.
http://www.westgard.com/saving-with-six-sigma.htm

CONCLUSION

- REDUCE COSTS OF POOR QUALITY
- CONTINUOUS MONITORING IS A KEY TO GOOD QUALITY
- PREPARE YOUR LAB FOR IQCP, CAP, ISO…

"Good things only happen when planned. Bad things happen on their own." – *Phillip Crosby, CLSI document QMS20-R*

HELPFUL RESOURCES



- CLSI EP23
- CLSI QMS20
- CLIA, CMS
- CAP
- Instrument and QC Manufacturers
- Westgard Website
- Visiun, Inc.

QUESTIONS?

The leader in laboratory analytics

www.visiun.com

800.941.4937

Tim Bickley, MT(ASCP),MBA,CPHIMS
Director of Sales-North America
Direct: 786-351-4805
Office: 786-360-6014
tim.bickley@visiun.com

List of Resources

CLSI EP23, QMS20-R
http://clsi.org/

Dr. James Westgard
http://www.westgard.com/
* http://www.westgard.com/essay42.htm#1
*http://www.westgard.com/hba1c-2014-partthree.htm
*http://www.westgard.com/saving-with-six-sigma.htm

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*Paul Keller, Six Sigma Deployment, Does Six Sigma Work in Smaller Companies?
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* Lusky K. INR practice gaps found in Q-Probes, March 2011, CAP Today

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*Bruce Jones, Leonas Bekeris, Raouf Nakhleh, Molly Walsh, Paul Valenstein (2009) Physician Satisfaction with Clinical Laboratory Services. Archives of Pathology & Laboratory Medicine: January 2009, Vol 133, pp38-43. http://www.archivesofpathology.org/doi/pdf/10.1043/1543-2165-133.1.38

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*Julie Hammerling, A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today, LabMed February 2012 vol. 43 no.2 41-44
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*http://laboratory-manager.advanceweb.com/Archives/Article-Archives/Quality-Control-and-Automation.aspx