Assessing the Quality of Your Lab's Test Results:

What We Learned at ARUP and How We Changed the Culture to Pursue Highest Quality

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Learning Objectives

- Identify common quality problems in the clinical laboratory
- Apply available strategies to obtain a current state assessment of laboratory quality
- Implement key milestones to keep quality improvement moving forward
- Identify roadblocks to achieving highest quality

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- Honorarium/Expenses: None
- Intellectual Property/Royalty Income: None

The Illusion of Quality

Eye Opening Experiences for Me – TTE Lab

- Trace and Toxic Element Laboratory
- Inductively-coupled plasma mass spectrometry
- 20 staff members
 - 1 x Supervisor, 1 x Lead Technologist, 1 x Technical Specialist, 17 x Bench technologists
- 20 different assays
- No QC failures for almost 6 months

Eye Opening Experiences for Me – cont.

- PT Failures with no explanations
 - QC all passed on the day of PT
- Staff complaints of difficult workload
- Obsession with NY guidelines, PT acceptance criteria
- Apparent disconnect between several bench technologists and patients
- A high quality lab that could be better but didn't know it!



Round 1

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Quality Control: Getting back to basics

Frederick G Strathmann, PhD, DABCC (CC, TC) January 2013 TTE Staff Meeting





Topics to cover

What is QC?

What can statistics tell us about our QC process?

How are we currently doing QC?

How is QC reviewed currently?

How could we change QC to enhance lab quality?

Why talk about QC?

As the lab evolves, our quality measures must evolve.

It is easy to disconnect from the *true goal of QC*.

Change is good, but only if it is the right change.

Reduce rework, increase efficiency, spend time on more appropriate aspects.

Ensure we never forget our responsibility to the "patient in the tube".

What is QC?

Intended to monitor the analytical performance of a measurement procedure and alert analysts to problems that might limit the usefulness of a test result.

Tells the analyst if the unknown (patient) results are valid

- 1. Test and method specific (materials, rules, number, frequency)
- 2. Define an "analytical run" or batch
- 3. Run QC and have an appropriate response plan



Key Features of Good QC

Prepped at the same time as patient samples and standards Any mistakes made with QC were likely made with patients too!

Represent the only known values and provide a reality anchor Like looking up the answers in the back of the book – VALIDITY!

Must be done consistently with ALL data collected, good or bad Allows a timeline of assay performance – PREDICTIVE and PREVENTATIVE

Rules identify real failures and are investigated to find a root cause Just enough QC with the right rules

Features of Bad QC

QC prepped independently of patients QC only validates calibration, can't find non-cognitive errors

QC repeated over and over until "it's in" 5% of the time, good QC is out. 5% of the time, bad QC is in.

Reporting in the range of "good QC" and ignoring "bad QC" *Might be fine once, but trends, shifts, and future problems are looming.*

Running QC before the instrument is ready Introduces unwanted variability (long term monitoring skewed)

A Closer Look: Our Current State

October, 2012

Test	N	Set Mean	Obv. Mean	Set SD	Obv. SD *	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
Lead WB Venous	375	1.7	1.72	0.3	0.125643	0.08	0.044199	17.64705 9	7.287862	5.89	1.100-2.300
Lead WB Venous	320	5.2	5.27	0.5	0.553706	0.144375	0.032298	9.615385	10.502404	4.83	4.200-6.200
Lead WB Venous	292	22.8	22.76	2.2	1.525024	-0.016656	-0.076027	9.649123	6.699468	6.65	18.400-27.200
Lead WB Venous	253	83.1	85.40	8.3	4.290246	0.276585	0.1562	9.987966	5.023963	4.42	66.500-99.700
Mang, Serum	20	1	1.01	0.5	0.298946	0.02	0.484211	50	29.598566	30.04	0.000-2.000
Mang, Serum	16	4.6	5.41	1	0.472537	0.80625	0.953333	21.73913	8.740578	9.84	2.600-6.600
Mang, Serum	13	14.7	18.14	2.2	1.08285	1.562937	1.710744	14.96598 6	5.969911	6.27	10.300-19.100
Mang, Serum	15	27.2	32.26	4.1	2.074608	1.234146	1.314634	15.07352 9	6.4309	4.56	19.000-35.400

How do we do this?

Find and identify assay or workflow problems inhibiting best practices for QC

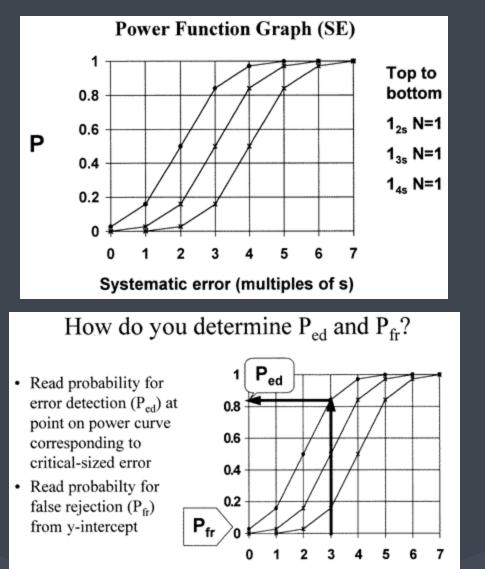
Establish "appropriate targets" for all QC

Standardize comments and troubleshooting steps in Master Control

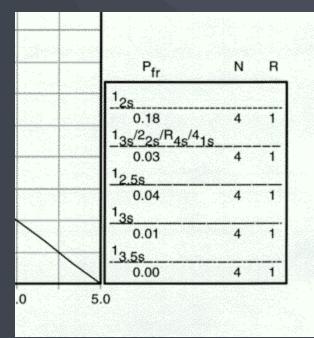
Modify rules to ensure appropriate balance of control *Not too much, not too little*

Adhere to good QC practice at all times QC prepped with patient samples No repeating of "out" QC Root cause of failed QC

Rule performance



Systematic error (multiples of s)



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QC Goals

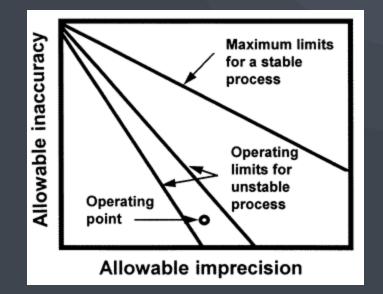
Total allowable error

Medical decision limits

Assay bias

Assay precision



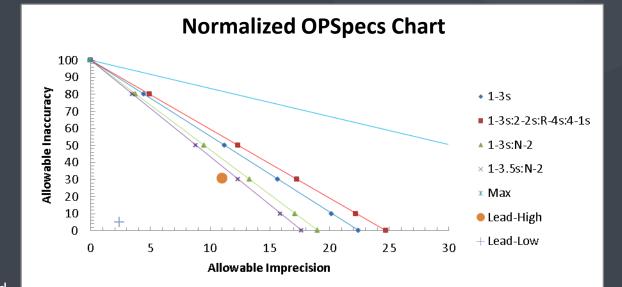


Example 1: Lead, WB

TEa = 10%

N = 4 1-3s: 0.01 P_{fr} 90% P_{ed} 1-3s+: 0.03 P_{fr} 90% P_{ed}

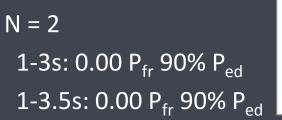
N = 2 1-3s: 0.00 P_{fr} 90% P_{ed} 1-3.5s: 0.00 P_{fr} 90% P_{ed}

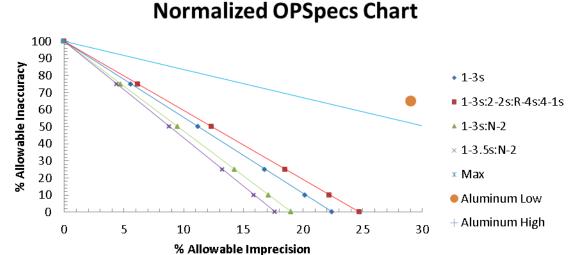


Example 2: Aluminum, U

TEa = 20%

N = 4 1-3s: 0.01 P_{fr} 90% P_{ed} 1-3s+: 0.03 P_{fr} 90% P_{ed}

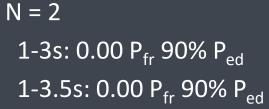


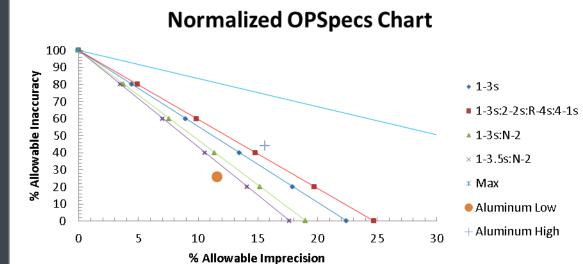


Example 2: Aluminum, U cont.

TEa = 50%

N = 4 1-3s: 0.01 P_{fr} 90% P_{ed} 1-3s+: 0.03 P_{fr} 90% P_{ed}





What's next?

Deeper analysis for all analytes in the lab

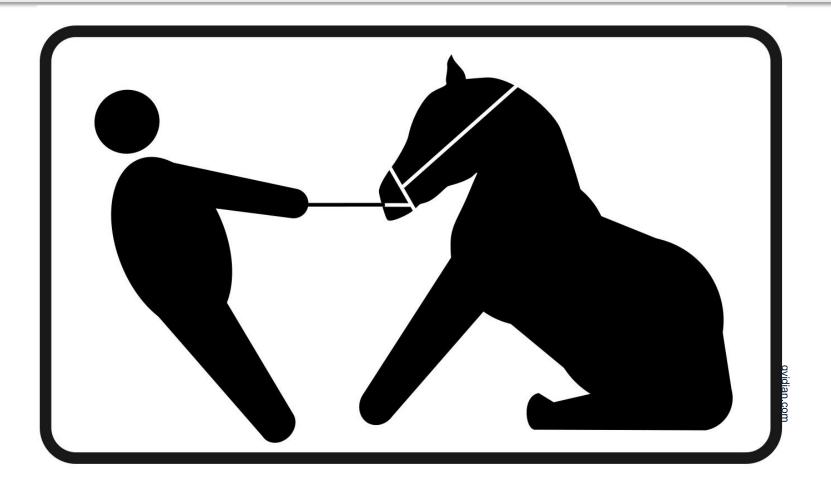
Standardization of comments and troubleshooting steps

Identify high yield, low false positive rules for each analyte

Establish more accurate goals for QC ranges (based on performance)

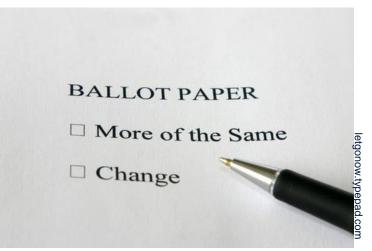
More fun, less work!

Progress Summary: January 2013 to September 2013



Why was there no progress?

- Staff didn't believe there was a problem.
- Management didn't understand how to change.
- Lots of MY ideas, lots of MY enthusiasm, no STAFF buy-in.





Round 2

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The Beginning of Buy-in

- A few more failed PTs
- A supervisor and a lead forced to "find the causes" with a medical director that wouldn't let up.
- Weekly Quality Assurance & Quality Control meetings
- Monthly QC review as a group
 - **Viewing the lab from my point of view**
- "Is it possible our QC is not as good as we think?"

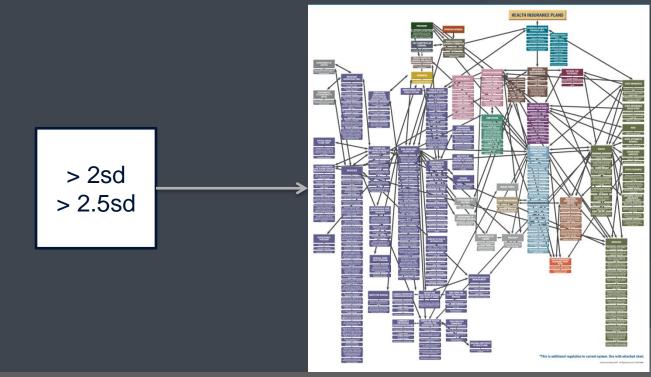
The Illusion of Quality

A Discussion of Outdated QC Approaches and Case Studies of Progress

> Frederick G. Strathmann ARUP Nuts and Bolts Series October 15, 2013

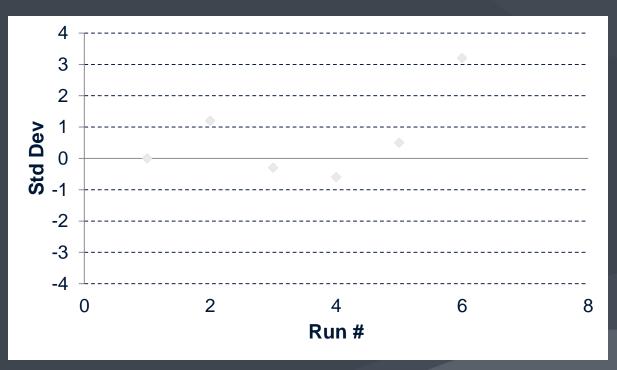
Common Mistake #1

Using a trigger with computer-based QC



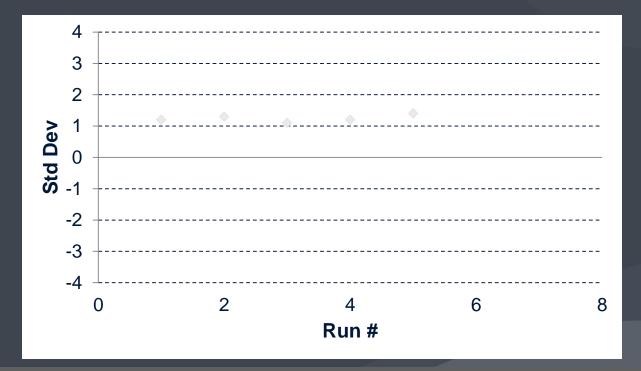
1-3s Rule

• Precision or Bias?



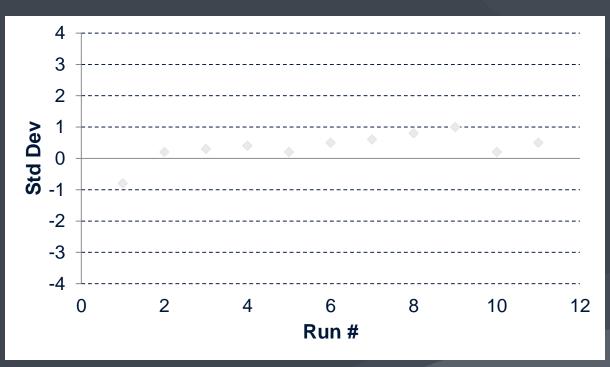
4_{1s} Rule

• Precision or Bias?



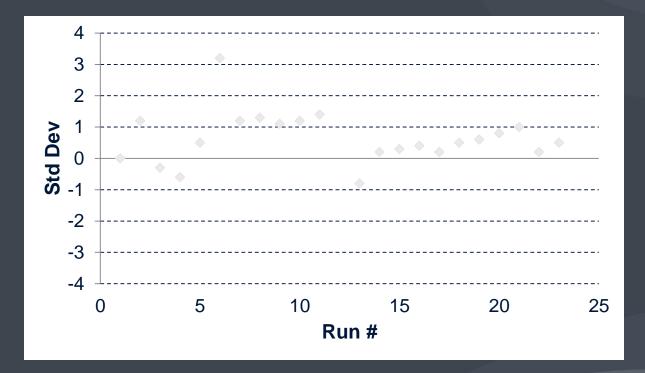
10x Rule

• Precision or Bias?



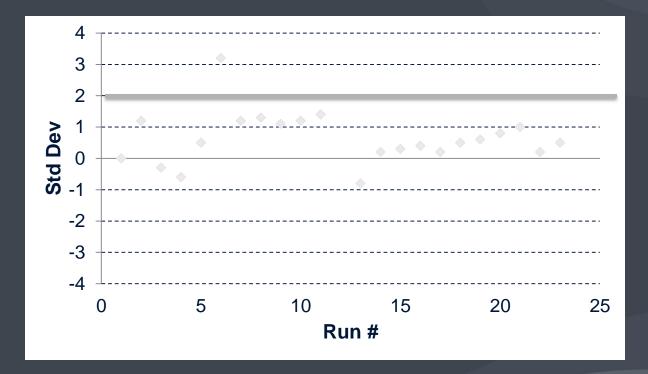
#1 Using a Trigger Rule

Few if any failures equals high quality...



#1 Using a Trigger Rule

Few if any failures equals high quality...



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Robots need work too...



Common Mistake #2

Cut and paste QC rules



#2 Cut and Paste QC Rules

If it works for them it should work for us...

- Probability of error detection
- Probability of false rejection
- Effectiveness of rule combinations

• How many of you KNOW your QC is working?

#2 Cut and Paste QC Rules

The more the merrier...

- Lab 1
 - 1-3s
- Lab 2
 - 1-3s/4-1s
- Lab 3

- 1-3s/2-2s/4-1s/R-4s/10x

Efficiency & Effectiveness of QC

0% bias; 2% CV

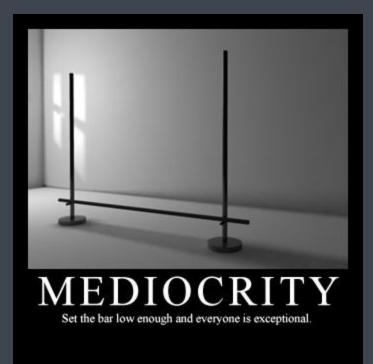
3% bias; 3% CV

Rule	Pfr	Ped	N	R
1-3.5s	0	0.066	2	1
1-3s	0	0.86	2	1
1-3s/2-2s/R-4s	0.01	0.94	2	1
1-2.5s	0.04	1	4	1
1-3s/2-2s/R-4s/4-1s/8x	0.03	1	4	2

Rule	Pfr	Ped	N	R
1-3.5s	0	0.01	2	1
1-3s	0	0.02	2	1
1-3s/2-2s/R-4s	0.01	0.03	2	1
1-2.5s	0.04	0.13	4	1
1-3s/2-2s/R-4s/4-1s/8x	0.03	0.18	4	2

Common Mistake #3

Unrealistic QC acceptance criteria





Example

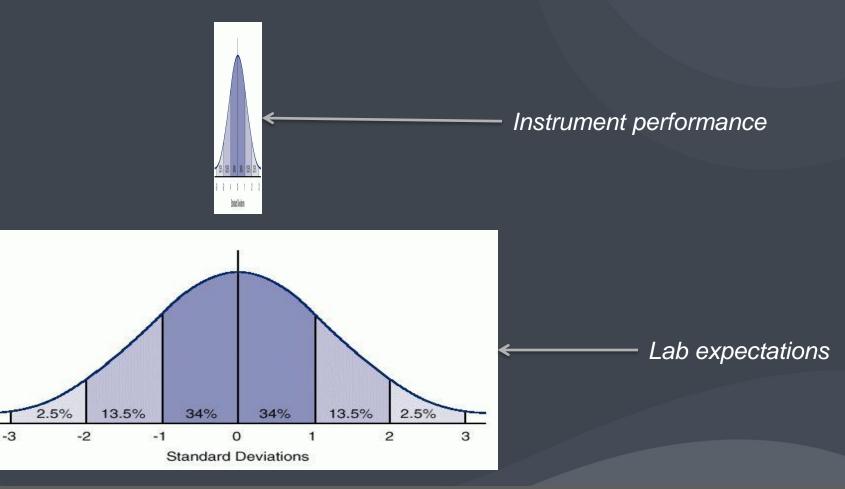
 Historically, we've set our acceptance criteria to match NY PT acceptance criteria.

- +/- 4 ug/dL at < 10 ug/dL (40%)

 Last month the CV for our 10ug/dL control was 5%

#3 Unrealistic QC Targets

Wider is better...

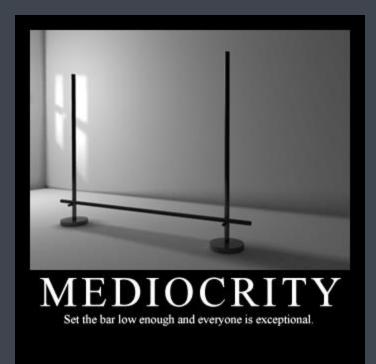


Outline

- Common Mistakes
- Necessary components of a QC plan
- Areas for continuous improvement
- Strategies for addressing quality weak points

Necessary Component #1

Appropriate targets and ranges





Identifying Weak Points

Test	N	Set Mean	Obv. Mean	Set SD	Obv. SD *	Z Score	Prev Mont Z	Set CV	Curr Month CV	Prev Month CV	Expected Range
Lead WB Venous	375	1.7	1.72	0.3	0.125643	0.08	0.044199	17.647059	7.287862	5.89	1.100-2.300
Lead WB Venous	320	5.2	5.27	0.5	0.553706	0.144375	0.032298	9.615385	10.502404	4.83	4.200-6.200
Lead WB Venous	292	22.8	22.76	2.2	1.525024	-0.016656	-0.076027	9.649123	6.699468	6.65	18.400-27.200
Lead WB Venous	253	83.1	85.40	8.3	4.290246	0.276585	0.1562	9.987966	5.023963	4.42	66.500-99.700

Necessary Component #2

 Rules that fit the assay



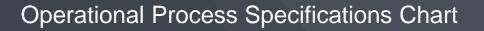
QC Goals

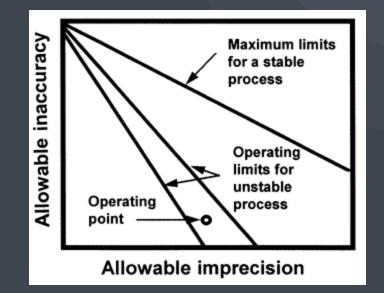
Total allowable error

Medical decision limits

Assay bias

Assay precision

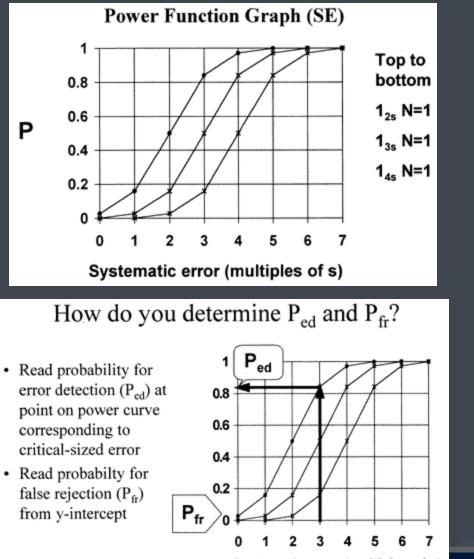




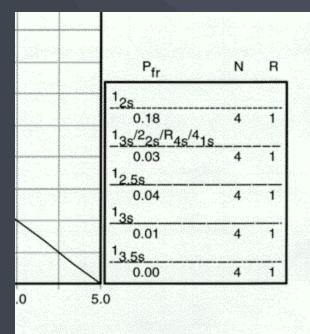
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Necessary Component #2

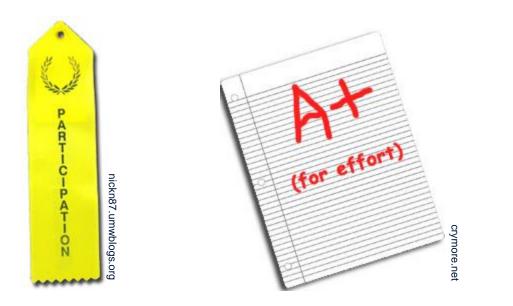


Systematic error (multiples of s)



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Almost...Not Quite



Strategy #1

Current state assessment

Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD -	Z Score	Prev Mont Z	Set OV	Curr Month CV	Prev Month CV	Expected Range
AS DMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	13.33	1.5	0.691375	-1.113333	-0.802381	10	5.188812	6.60	12.000-18.000
AS DMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	102	94.49	10.2	4.422419	-0.736275	-0.392157	10	4.680304	6.40	81.600-122.400
AS II	TEC Fractionation	881 AS UF LEVEL I	72778.1	14	21	22.69	21	2.472575	0.802721	1.636655	10	10.899259	8.37	18.800-25.200
AS MMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	14.03	1.5	0.980803	-0.65	-0.385714	10	6.993245	6.87	12.000-18.000
AS MMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	103	94.43	10.3	3.89576	-0.832039	-0.449376	10	4.125554	5.24	82,400-123,600
AS Organic	TEC Fractionation	881 AS UF LEVEL I	72778.1	20	52	44.19	5.2	1.71584	-1.501923	-1.120879	10	3.882968	6.19	41.600-62.400
AS Organic	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	304	341.51	39.4	19.552484	-1.332234	-1.065708	10	5.725298	5.64	315.200-472.800
AS V	TEC Fractionation	881 AS UF LEVEL I	72778.1	20	13	12.68	1.3	1.079413	-0.25	0.615385	10	8.516076	7.25	10.400-15.600
AS V	TEC Fractionation	861 AS UF LEVEL II	72778.2	18	98	95.40	9.8	4.631732	-0.265306	0.184767	10	4.855085	6.00	78.400-117.600
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	10	1.3	1.10	0.5	0.316228	-0.4	-0.6	38.481538	28.747979	0.00	0.300-2.300
Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	10	8.4	5.50	1	0.527048	-0.9	-0.9	15.625	9.58298	9.98	4.400-8.400
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	8	1.9	1.88	0.5	0.353553	-0.05	-0.05	28.315789	18.856181	18.86	0.900-2.900
Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	8	5.4	5.38	1	0.517549	-0.025	-0.4	18.518519	9.828822	0.00	3.400-7.400
Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	37635	8	0.58	0.53	0.1	0.138873	-0.35	0.929412	17.857143	28.452003	18.85	0.360-0.760
Copper, Free	TEC ICP MS Dig	881 CU FREE LEVEL I	83459	25	15	14.68	1.4	1.091253	-0.228571	0.069333	9.333333	7.433604	9.85	12:200-17.800
Copper, Free	TEC ICP MS Dig	881 CU FREE LEVEL II	69152	22	3.3	3.37	0.53	0.211979	0.137221	0.410172	16.060606	6.285089	9.53	2.240-4.380
Copper, Free	TEC ICP MS Dig	861 CU FREE NIST	1643E	19	2.28	2.25	0.3	0.102028	-0.108772	0.22983	13.157895	4.53981	4.88	1.680-2.880
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	2	2.52	2	0.557708	0.259808	0.383409	100	22.134584	23.27	-2.000-6.000
CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	28	3	2.78	1	0.753833	-0.218077	0.210455	33.333333	27.097549	18.77	1.000-5.000
FE Weight	TEC ICP M8 Dig	861 TISSUE LEVEL I	1577C	28	2	2.62	2	0.638045	0.308077	0.398571	100	24.312198	28.78	-2.000-8.000
FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	28	3	2.77	1.2	0.74372	-0.191028	0.285227	40	26.841642	24.21	0.600-5.400
Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	81.5	81.38	28.2	18.042157	-0.004384	0.37637	34.601227	22.171098	22.63	25.100-137.900
Hen Conner Cont	TEC ICP MS Dia	ARI TISSUE LEVEL I	TE050410	28	58	6.77	17	1 552487	0.099548	1.040107	30.357143	28.000772	21.98	2 200-9 000

Strategy #2

Ask the staff

Poor performing assays
Assays not working well
too busy Solving problems individually
Lack of staffing procedural inflexibility short on time
pulling long hours
Instruments not functioning properly
Imited amount of automation
Personal opinion
always very rushed

Quality Control Overhaul

	A	В	C	D	E	F	G		
16	0	38.75	1-3s/2of3-2s/R-4s/3-1s/6x	6	1	0.5	0.07	** AU [+	
17	100	0	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05	10	10
18	0	34.375	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05	0	
19	100	0	1-2.5s	6	1	0.5	0.06	0 5 10 15 20 25 30 35 40 45 5	
20	0	33.75	1-2.5s	6	1	0.5	0.06	Allowable Imprecision	Allowable Imprecision
21	100	0	1-3s	6	1	0.5	0.01		
22	0	29.375	1-35	6	1	0.5	0.01		
23	100	0	1-3.5s	6	1	0.5	0		
24	0	25	1-3.5s	6	1	0.5	0		
25	100	0	Max		· ·	0.5			
26	0	50	Max						
20	0	50	Ivida						
27	100	0	1-2s	4	1	0.0	0.18		
						0.9			
29	0	28.75	1-2s	4	1	0.9	0.18		
30	100	0	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03		
31	0	25.625	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03		
32	100	0	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03		
33	0	29.07	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03	Normalized OPSpecs Chart	Normalized OPSpecs Cha
34	100	0	1-2.5s	4	1	0.9	0.04		N = 4; 50% AQA
35	0	25	1-2.5s	4	1	0.9	0.04		N, 30/0AQA
36	100	0	1-3s	4	1	0.9	0.01	100 🎭	100 👞
37	0	21.875	1-3s	4	1	0.9	0.01	90 Multi	No.
38	100	0	1-3.5s	4	1	0.9	0		90
39	0	18.75	1-3.5s	4	1	0.9	0		80
40	100	0	Max					91-3s	70
41	0	50	Max					60 01-3.5s	
42									<u><u><u></u></u> 50</u>
43	100	0	1-2s	4	1	0.5	0.18	40 • Mult8xR2	4 40
44	0	37.5	1-2s	4	1	0.5	0.18		
45	100	0	1-3s/2-2s/R-4s/4-1s	4	1	0.5	0.03		
46	0	31.25	1-3s/2-2s/R-4s/4-1s	4	1	0.5	0.03		+ 20 +
47	100	0	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.5	0.03	10	10
48	0	36.23	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.5	0.03	0	• - O E
49	100	0	1-2.5s	4	1	0.5	0.04		0 0 5 10 15 20 25 30
50	0	31.875	1-2.5s	4	1	0.5	0.04	Allowable Imprecision	Allowable Imprecision
51	100	0	1-3s	4	1	0.5	0.04		
52	0	26.875	1-35	4	1	0.5	0.01		
52	100	26.875	1-35 1-3.5s	4	1	0.5	0.01		
53		23.75	1-3.5s	4	1	0.5	0		
	0			4	1	0.5	U		
55	100	0	Max						
56	0	50	Max						
57									
58	100	0	1-2s	3	1	0.9	0.14		
59	0	25.625	1-2s	3	1	0.9	0.14		
60	100	0	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02	Newselized OBC see Chest	Name lined OPC Chai
61	0	23.75	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02	Normalized OPSpecs Chart	Normalized OPSpecs Char
62	100	0	1-3s/2of3-2s/R-4s/3-1s/6x	3	2	0.9	0.03	N = 3, 90% AOA	N = 3; 50% AQA
63	0	28.65	1-3s/2of3-2s/R-4s/3-1s/6x	3	2	0.9	0.03		
64	100	0	1-2.5s	3	1	0.9	0.03	• 1-2	
65	0	25	1-2.5s	3	1	0.9	0.03	100 🌯	100 🌜
66	100	0	1-3s	3	1	0.9	0.01		
67	0	20	1-3s	3	1	0.9	0.01	30 E 1 2 2	
68	100	0	1-3.5s	3	1	0.9	0	so •1-3s	50
69	0	18.125	1-3.5s	3	1	0.9	0	175-	₹ 70
70	100	0	Max					2 70 Max	
14 4		Custom Rule	es 📜 Lead WB 🖉 Assa	y Next	/ 🔁 /				····· • •
and the second second									LINIVERSITY OF LITAH I DEPARTMENT OF PA

ARUP LABORATORIES | NATIONAL REFERENCE LABORATORY

UNIVERSITY OF UTAH | DEPARTMENT OF PATHOLOG

Improvement Area #1

QC rules evaluated on a continuous basis

	A	В	Concession Concession	D	E	F	G H	J	K L	MNO	P Q P	S S	TU	V V	×	Ŷ						
16	0	38.75	1-3s/2of3-2s/R-4s/3-1s/6z	6	1	0.5	0.07	10	+ \		100 million (1997)		10 +									
	100	0	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05						- E									
	0	34.375	1-3s/2of3-2s/R-4s/3-1s	6	1	0.5	0.05	0 5	10 15	20 25 30 35	40 45 5		0 5	10 15 Z	20 25 3	30						
	100	0	1-2.5s	6	1	0.5	0.06		10 15	Allowable Imprecision	** ** *				Allowable Imprecisio							
2.0	0	33.75	1-2.5s	6	1	0.5	0.06			Hib Walle Implectabili												
	100	0	1-3s	6	1	0.5	0.01															
22	0	29.375	1-3s	6	1	0.5	0.01															
23	100	0	1-3.5s	6	1	0.5	0															
24	0	25	1-3.5s	6	1	0.5	0															
25	100	0	Max																			
26	0	50	Max																			
27																						
28	100	0	1-2s	4	1	0.9	0.18															
29	0	28.75	1-2s	4	1	0.9	0.18													-	-	
30	100	0	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03															
31	0	25.625	1-3s/2-2s/R-4s/4-1s	4	1	0.9	0.03	Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD +	Z Score	Prev Mont Z	Secov	Ourr Month OV	Prev Month CV	Expected Range
32	100	0	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03															
33	0	29.07	1-3s/2-2s/R-4s/4-1s/8x	4	2	0.9	0.03	AS DMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	13.33	1.5	0.691375	-1.113333	-0.802381	10	5.188812	6.60	12.000-18.000
	100	0	1-2.5s	4	1	0.9	0.04	AS DMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	102	94.49	10.2	4.422419	-0.738275	-0.392157	10	4.680304	6.40	81.600-122.400
	0	25	1-2.5s	4	1	0.9	0.04	AS II	TEC Fractionation	861 AS UF LEVEL I	72778.1	14	21	22.69	21	2.472575	0.802721	1.636055	10	10.899259	8.37	18.800-25.200
	100	0	1-3s	4	1	0.9	0.01	AS MMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	14.03	1.5	0.980803	-0.65	-0.385714	10	6.993245	6.87	12.000-18.000
	0	21.875	1-35	4	1	0.9	0.01	AS MMA	TEC Fractionation	861 AS UF LEVEL II	72778.2	20	103	94.43	10.3	3.89578	-0.832039	-0.449376	10	4.125554	5.24	82.400-123.600
	100	0	1-3.5s	4	1	0.9	0	AS Organic	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	52	44.19	5.2	1.71584	-1.501923	-1.120879	10	3.882968	6.19	41.600-62.400
	0	18.75	1-3.5s	4	1	0.9	0	AS Organic	TEC Fractionation	881 AS UF LEVEL II	72778.2	20	394	341.51	39.4	19.552484	-1.332234	-1.085708	10	5.725298	5.64	315.200-472.800
	100	0	Max			0.0		AS V	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	13	12.68	1.3	1.079413	-0.25	0.615385	10	8.516076	7.25	10.400-15.600
	0	50	Max					AS V	TEC Fractionation	861 AS UF LEVEL II	72778.2	18	98	95.40	9.8	4.631732	-0.265306	0.184767	10	4.855085	6.00	78.400-117.600
42	•	00	14104					Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	10	1.3	1.10	0.5	0.316228	-0.4	-0.6	38.481538	28.747979	0.00	0.300-2.300
	100	0	1-2s	4		0.5	0.18	Antimony Blood	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	10	6.4	5.50	1	0.527048	-0.9	-0.9	15.625	9.58268	9.98	4.400-8.400
	0	37.5	1-25	4		0.5	0.18	Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL I	68819.1	8	1.9	1.88	0.5	0.353553	-0.05	-0.05	28.315789	18.856181	18.86	0.900-2.900
	100	0	1-3s/2-2s/R-4s/4-1s	4		0.5	0.03	Bismuth WB	TEC ICP MS Dig	861 BLD DIG LEVEL II	68819.2	8	5.4	5.38	1	0.517549	-0.025	-0.4	18.518519	9.626822	0.00	3.400-7.400
	0	31.25	1-3s/2-2s/R-4s/4-1s	4		0.5	0.03	Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	37635	8	0.56	0.53	0.1	0.138873	-0.35	0.929412	17.857143	28.452003	18.85	0.380-0.780
	100	0	1-3s/2-2s/R-4s/4-1s/8x	-		0.5	0.03	Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL I	83459	25	15	14.68	1.4	1.091253	-0.226571	0.069333	9.333333	7.433804	9.85	12.200-17.800
	0	36.23	1-3s/2-2s/R-4s/4-1s/8x		2	0.5	0.03	Copper, Free	TEC ICP MS Dig	861 CU FREE LEVEL II	69152	22	3.3	3.37	0.53	0.211979	0.137221	0.410172	16.060606	6.285089	9.53	2.240-4.380
	100	0	1-2.5s	1		0.5	0.04	Copper, Free	TEC ICP MS Dig	861 CU FREE NIST	1643E	19	2.28	2.25	0.3	0.102028	-0.108772	0.22983	13.157895	4.53981	4.88	1.680-2.680
	0	31.875	1-2.5s	4	1	0.5	0.04	CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	2	2.52	2	0.557708	0.259808	0.363409	100	22.134584	23.27	-2.000-8.000
	100	31.875	1-3s	*		0.5	0.04	CU Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	26	3	2.78	1	0.753833	-0.218077	0.210455	33.333333	27.097549	18.77	1.000-5.000
	0		1-35	-		0.5	0.01	FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	2	2.62	2	0.638045	0.308077	0.398571	100	24.312198	28.78	-2.000-8.000
	100	26.875		4	1		0.01	FE Weight	TEC ICP MS Dig	861 TISSUE LEVEL II	TE050410	28	3	2.77	1.2	0.74372	-0.191028	0.285227	40	28.841642	24.21	0.600-5.400
			1-3.5s 1-3.5s	4	1	0.5		Hep Copper Cont	TEC ICP MS Dig	861 TISSUE LEVEL I	1577C	28	81.5	81.38	28.2	18.042157	-0.004384	0.37637	34.601227	22.171098	22.63	25.100-137.900
	0	23.75		4		0.0	0	Hen Conner Cont	TEC ICP MS DW	ART TIRSUE UPVEL I	TE050410	28	58	5.77	17	1.552487	0.000548	1.040107	30 357143	28 0/0772	21.88	2 200-0 000
	100	50	Max Max																			
56	U	50	Max																			
	100	0	10-	3			0.14															
	100		1-2s	3	1	0.9	0.14															
		25.625	1-2s	3	1	0.9						_										
	100	*	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02		Normaliz	ed OPSpecs Chart				Normalize	d OBSpace	Char						
	0	23.75	1-3s/2of3-2s/R-4s-/4-1s	3	1	0.9	0.02				😑 Level II											
	100	0	1-3s/2of3-2s/R-4s/3-1s/6z	3	2	0.9	0.03		N =	3; 90% AQA	+ Level I	H		N = 3	3; 50% AQA							
	0	28.65	1-3s/2of3-2s/R-4s/3-1s/6z	3	2	0.9	0.03				• 1-2:											
	100	0	1-2.5s	3	1	0.9	0.03	-				H										
	0	25	1-2.5s	3	1	0.9	0.03	100			• Multi		100 🏡									
	100	0	1-3s	3	1	0.9	0.01	90			1-25s	H	90									
01	0	20	1-35	3	1	0.9	0.01		Sec. 1		 1-3s 			· · ·								
	100	0	1-3.5s	3	1	0.9	0	80	and the second second		• 1-3.5s		80	1 mar 1								
	0	18.125	1-3.5s	3	1	0.9	0	a 70	1 mar.			H 3	70									
70	100	n Istom Rule	Max Lead WB Ass	by Movt	/07	/			m)		• Max		- F	1011 .								
	n u	IS COLLECTED	Eedu WD / ASS	ay Next	1 Col /	/				U •		_				F						

Improvement Area #2

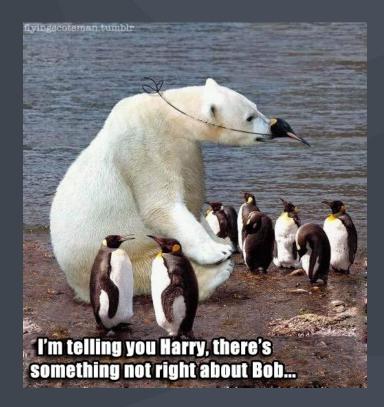
QC troubleshooting plan optimization

- Track success
- Track failures
- Evaluate effectiveness
- Enhance technical competency amongst staff

Improvement Area #3

Assay improvements

- Identify the real problems
- Fix the problems you have
- Balance or combine SO conversions with improvements

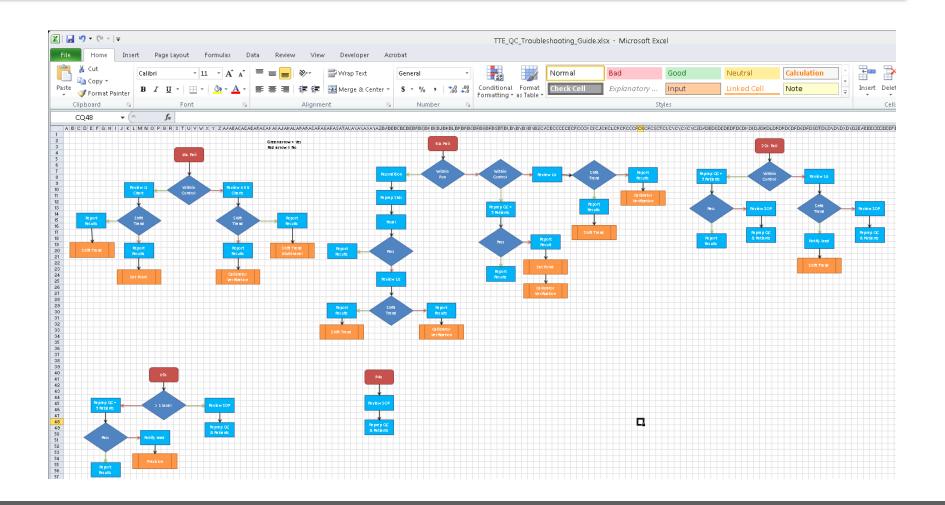


And Then it Happened

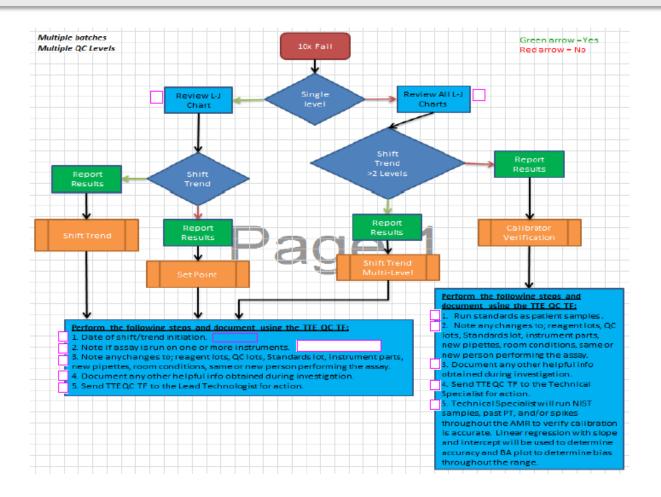
Current State Assessment Completed

	1	A	в	C 1	D	E	F	G	н ј ј	K	M N O	P Q R	S	тυ	V V	X	Y						
U 1 Links 341-05 4 1 6 3 0 1 Links 341-05 4 1 6 3 1<	16	0		1-3s/2of3-2s/B-4s/3-1s/6s	6	1	0.5			+		1000		au = +									
0 1/2	17	100			6	1	0.5	0.05	10			100 million (100 m		10									
0 0 1 0	18	0	34.375		6	1	0.5							0									
a 107 112 112 11 112<		100	0		6	1	0.5	0.06	0 5			40 45 50		0 5									
Image: Note of the second s	20		33,75		6	1					Allowable Imprecision					Alloweble Imprecisio	'n						
2 0 100 </td <td></td> <td>100</td> <td>0</td> <td></td> <td>6</td> <td>1</td> <td>0.5</td> <td>0.01</td> <td></td>		100	0		6	1	0.5	0.01															
10 0 0 10 10 0 0 10 0 0 10 0<	22		29.375		6	1																	
18 0 0 5 155 4 1 0 0 19 0 </td <td></td> <td>100</td> <td>0</td> <td>1-3.5s</td> <td>6</td> <td>1</td> <td>0.5</td> <td>0</td> <td></td>		100	0	1-3.5s	6	1	0.5	0															
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a b b Mat A A B		100	0	Max																			
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10 0 55.55 1000 2001-001-00 1000 Test Test Control test N feed mathematical N Method N Sec 200-00-00 Sec 200-00		100			4	1																	
20 0 10 100 </td <td></td> <td></td> <td>25.625</td> <td></td> <td>4</td> <td>1</td> <td></td> <td></td> <td>Test</td> <td>Test Site</td> <td>Control Name</td> <td>Control Lot</td> <td>N</td> <td>Set Mean</td> <td>Obv. Mean</td> <td>Set SD</td> <td>Obv. SD -</td> <td>Z Score</td> <td>Prev Mont Z</td> <td>SecOV</td> <td>Ourr Month OV</td> <td>Prev Month CV</td> <td>Expected Range</td>			25.625		4	1			Test	Test Site	Control Name	Control Lot	N	Set Mean	Obv. Mean	Set SD	Obv. SD -	Z Score	Prev Mont Z	SecOV	Ourr Month OV	Prev Month CV	Expected Range
0 0		100			4	2																	
81 00 0 1252 4 1 0.3 0.4 92 0 252 4 1 0.3 0.4 1 0.3 0.4 1 0.3 0.4 1 0.3 0.4 1 0.3 0.4 1 0.3 0.4 1 0.3 0.4 1 0.3 0.4 1 0.3 0.4 0.3	33				4	2			AS DMA	TEC Fractionation													
g b b c		100			4	1													-0.392157				
Bit No 0 132 4 1 0.0 0.0 132 4 1 0.0 0.0 132 4 1 0.0 0.0 132 4 1 0.0 0			25		4	1				TEC Fractionation		72778.1	14	21	22.69	21	2.472575		1.638855	10	10.899259	8.37	18.800-25.200
$ \begin{array}{c c c c c c c c c c c c c c c c c c c $		100			4	1			AS MMA	TEC Fractionation	861 AS UF LEVEL I	72778.1	20	15	14.03	1.5	0.980803	-0.65	-0.385714	10	6.993245	6.87	12.000-18.000
30 00 0 1355 4 1 0.9 0 1355 4 1 0.9 0 1355 4 1 0.9 0 1355 4 1 0.9 0 1355 4 1 0.9 0 1355 1355 4 1 0.9 0 1355 13	37		21875		4	1												-0.832039					
30 0 13.55 4 1 0 0 40 00 0 Mu - <th< td=""><td></td><td>100</td><td></td><td></td><td>4</td><td>1</td><td></td><td></td><td>AS Organic</td><td>TEC Fractionation</td><td></td><td></td><td>20</td><td></td><td></td><td></td><td></td><td>-1.501923</td><td></td><td></td><td></td><td></td><td></td></th<>		100			4	1			AS Organic	TEC Fractionation			20					-1.501923					
00 00 Main VIII VIIII VIIIII VIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII						1												-1.332234					
41 0 90 Mai																							
42	41		50						AS V	TEC Fractionation	861 AS UF LEVEL II	72778.2	18	98		9.8			0.184767		4.855085		78.400-117.600
40 00 0 1/2 4 1 0.5 0.8 0.8 0.8 1 0.850 1 0.850 1.8 0.8	42															0.5							
44 0 0.75 1.22 4 1 0.5 0.8 <td></td> <td>100</td> <td>0</td> <td>1-2:</td> <td>4</td> <td>1</td> <td>0.5</td> <td>0.18</td> <td></td>		100	0	1-2:	4	1	0.5	0.18															
45 90 0 0 1/22/2/14-14/15 4 1 0.5 0.00 1/22/2/14-14/15 4 1 0.5 0.00 1/22/2/14-14/15 4 1 0.5 0.00 1/22/2/14-14/15 4 1 0.5 0.00 1/22/2/14-14/15 4 2 0.5 0.00 1/22/2/14-14/15 4 2 0.5 0.00 1/22/2/14 0/22/2/14	44				4	1																	
46 0 3125 13422/2m14444 4 1 0.5 0.00 47 90 0 13422/2m1444 4 2 0.5 0.00 48 0 9223 13422/2m1444 4 2 0.5 0.00 48 0 9223 13422/2m1444 4 2 0.5 0.00 50 0 0 1342/2m1444 4 2 0.5 0.00 50 0 0.523 1342/2m1444 4 2 0.5 0.00 0.41072 4.2467 0.40024 4.84 0.2246/4.86 50 0 0.523 1342/2m1444 4 1 0.5 0.01 0.02 0.01 2.28 1.01172 4.2467 0.40024 4.83 0.2246/4.86 4.83 0.2246/4.86 4.83 0.2246/4.86 4.83 0.2246/4.86 4.83 0.2246/4.86 4.83 0.2246/4.86 4.83 0.246/4.86 0.2326/4.86 0.2326/4.86 0.2326/4.86 0.2326/4.86 0.2326/4.86 0.2326/4.86 0.2326/4.86 0.2326/4.86 0.2326/4.86		100			4	1				TEC ICP MS Dig	861 BLD DIG LEVEL II		8			1	0.517549		-0.4		9.628822		
47 90 0 1-302-24rH-44+1/bit 4 2 0.0 0 48 10 0.0 1-302-24rH-44+1/bit 4 2 0.0 0.0 48 10 0.0 1-255 4 1 0.5 0.0 49 10 0.0 1-255 4 1 0.5 0.04 10 0.0 1-255 4 1 0.5 0.04 10 0.0 1-335 4 1 0.5 0.04 10 0.0 1-335 4 1 0.5 0.04 10 0.0 1-335 4 1 0.5 0.04 10 0.0 1-335 4 1 0.5 0.04 10 0.0 1-335 4 1 0.5 0.0 11 0.60 11 0.60 11 0.60 11 0.60 11 0.60 11 0.60 11 0.60 11 0.60 0.1 11 0.60 0.1 11 0.60 0.1 11 <td>46</td> <td></td> <td></td> <td></td> <td>4</td> <td>1</td> <td></td>	46				4	1																	
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90 0 31875 1252 4 1 0.5 0.0 90 0 0 133 4 1 0.5 0.0 90 0 0 133 4 1 0.5 0.0 90 0 0 133 4 1 0.5 0.0 90 0 0 133 4 1 0.5 0.0 90 0 0 1355 4 1 0.5 0.0 91 0.0 0 1355 4 1 0.5 0.0 91 0.0 22.75 133.55 4 1 0.5 0.0 <t< td=""><td></td><td>100</td><td></td><td></td><td>4</td><td>1</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>2.28</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>		100			4	1								2.28									
91 00 0 132 4 1 0.5 0.0 92 0 2.875 13.4 4 1 0.5 0.0 93 00 0 13.5 4 1 0.5 0.0 93 00 0 13.5 4 1 0.5 0.0 93 00 0 13.5 4 1 0.5 0 94 0 13.5 4 1 0.5 0 95 00 23.75 13.65 4 1 0.5 0 95 00 0 Mat 1 0.5 0 95 00 0 Mat 1 0.5 0 96 00 0 Mat 1 0.5 0 97 0 0 Mat 1 0.3 0.44 98 00 0 Mat 1 0.3 0.44 98 0 2.375 1.32.64/81 0.44 0.3 0.44 98 0 0.43/14 0.3 0.44 0.4 0.44 98 0 2.375 1.32.64/24 0.40 99	50				4	1								2									
52 0 28.875 1.32 4 1 0.5 0.0 53 00 0 1.355 4 1 0.5 0.0 54 0 22.75 1.355 4 1 0.5 0 150.00 160.00 1355 4 1 0.5 0 150.00		100			4	1								3									
90 00 0 13.5s 4 1 0.5 0 15.2s 3 2.77 11.2 0.842/2 -0.100/8 0.282/7 4.60 28.44/962 24.21 0.400/82 24.21			26.875		4	1								-									
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Troubleshooting Workflow Developed – *By Me*



Troubleshooting Tools Developed – With Staff



Organizational Support

- QC Subcommittee formed from LIS SuperUsers
- SOP written based upon TTE Lab process
- Presentations to Group Managers
- Presentations to Supervisors
- Workshops organized for interested labs
 - Hands on with lab data

Illusion of Quality - Indeed

It can be painful to be the leader... •

New folder

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Fix it. Keep fixing it.

- Track success
- Track failures

- Evaluate effectiveness
- Enhance technical competency amongst staff

Where are we now?

TTE Lab: Current State Assessment 6 mo. post "go-live"

- Not 1 failed PT
- Monthly QC review < 15 minutes
- Laboratory staff engaged in quality
 - Looking at LJ charts "because they're interesting"
 - Amazing ideas about QC failures and what to do
 - Appreciation for what and why "Patient in the tube"
- A nearly complete culture change

Organizational Current State

- Five full workshops with requests for more
 - Current State Assessment: Part I and Part II
- Follow-up workshops in preparation
 - Designing a QC Troubleshooting Plan: Part I and Part II
 - Pulling the trigger on your first change: Part I
 - Follow up post go-live: Part II

What I learned from all of this.

- It is not enough to state the obvious.
- It is not enough to provide tools for change.
- Even though staff "should know this stuff" they don't always know how to apply it.
- Someone has to drive preferably someone with a backbone.
- Everyone has to be involved somehow.