The benefit of using an Independent Quality Control:

Case Studies

A real life/real Lab experience 2014 to 2019

Labroots **Bio-Rad Webinar** **Oct-21-2020**

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Disclaimer

- No Financial conflicts to disclose.
- Information in this presentation and examples are for Educational purposes only.
- No product advice or endorsement.
- Not promoting any service or product.

Learning Objectives

Participants will be able to:

1. Identify at least 2 benefits Independent Q.C. can provide when troubleshooting an out-of-control event.
2. Recognize at least 2 advantages an interlaboratory comparison program can provide.

Agenda

4 case study examples

1. **Unity** Monthly Peer comparison **revealed marginal performance**. Example **"GGT"** calibration factor.

2. **Unity** Monthly Peer comparison **provided confidence**. Example **"Vancomycin"**

3. **Unity** Monthly Peer comparison (19-02-2019), 2 level controls outside the acceptable 2 SDI of Peer group (69 Labs, 2434 points). Example **"Micro albumin Urine Albumin"** Calibrator.

4. **Free T3**. New 6 point calibrator and new Assay file. **Stop test**.

Interpretation

QCNet Monthly Report

Unity™ Laboratory Performance Overview

Immunoassay Plus • Lot 40930 • Exp 28–Feb–2019

November 2017 • Lab 681268

CLINICAL CHEMISTRY

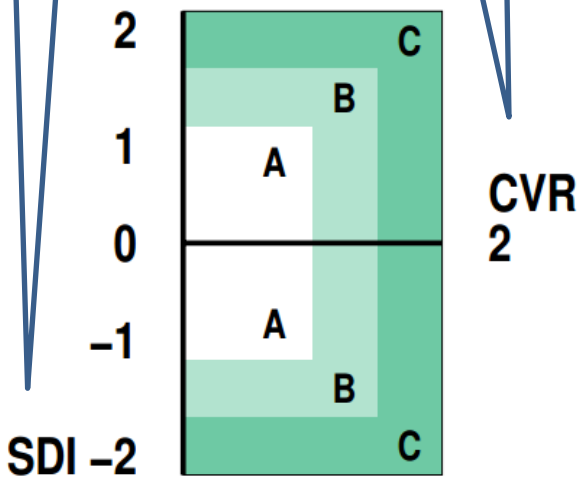
SDI=How many S.D away from the over all mean

Bias

Precision

Suggested Interpretation

The following interpretations should be used as guidelines only. Each laboratory should determine whether a review of bias and/or precision is necessary and whether corrective actions may be required.



A Acceptable Performance.

B Acceptable to Marginal Performance – May indicate the need to investigate test system bias or precision.

C Marginal Performance – Corrective action may be necessary.

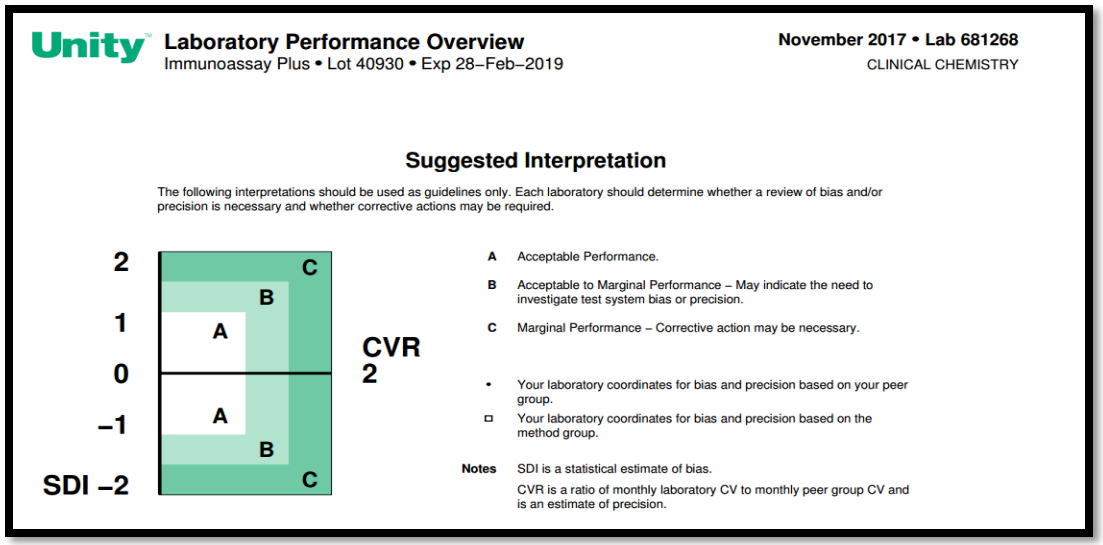
• Your laboratory coordinates for bias and precision based on your peer group.

□ Your laboratory coordinates for bias and precision based on the method group.

Notes SDI is a statistical estimate of bias.

CVR is a ratio of monthly laboratory CV to monthly peer group CV and is an estimate of precision.

Formulas



Unity Laboratory Performance Overview
Immunoassay Plus • Lot 40930 • Exp 28–Feb–2019

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CLINICAL CHEMISTRY

Suggested Interpretation

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• Your laboratory coordinates for bias and precision based on your peer group.

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Notes SDI is a statistical estimate of bias.

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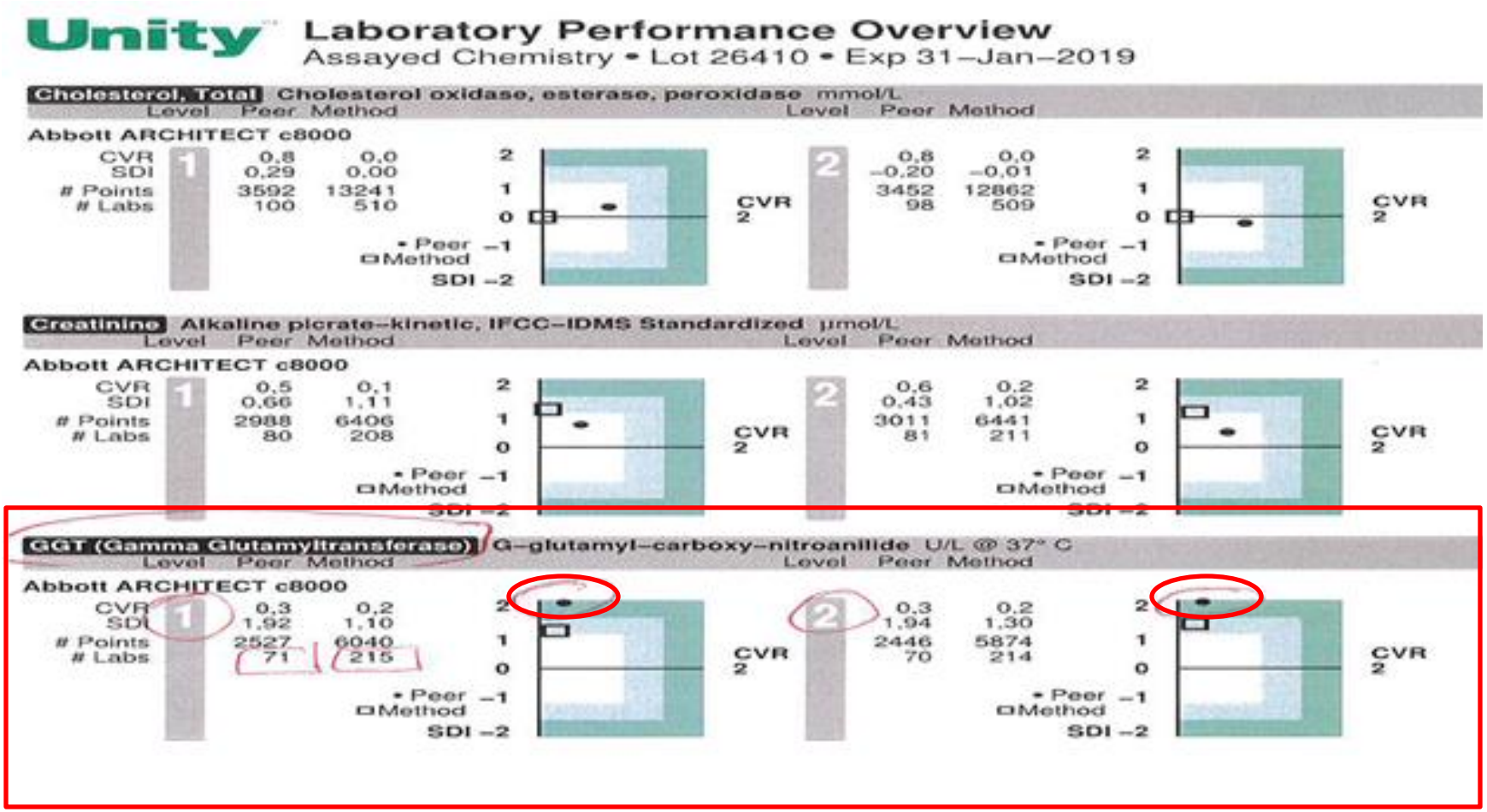
S.D.I and C.V.R

$$\text{S.D.I} = \text{Standard Deviation Index} = \left[\frac{\text{Lab Mean} - \text{Peer Group Mean}}{\text{Peer group S.D}}\right] = \text{Bias (how many S.D away from the overall Mean)}$$

$$\text{C.V.R} = \text{C.V. Ratio} = \left[\frac{\text{Lab C.V (monthly)}}{\text{Peer C.V (monthly)}}\right] = \text{Precision}$$

Case Study # 1

G.G.T (Gamma-Glutamyl Transferase)



Unity "Laboratory Comparison Report"

GGT (October 2017)

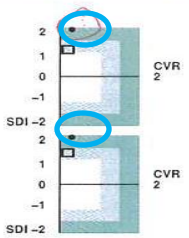
Unity Laboratory Comparison Report
Assayed Chemistry • Lot 26410 • Exp 31–Jan–2019

October 2017 • Lab 681271
CLINICAL CHEMISTRY

GGT (Gamma Glutamyltransferase) G–glutamyl–carboxy–nitroanilide U/L @ 37° C

Abbott ARCHITECT c8000

Level		Mon	Cum
• Peer CVR	1	0,3	0,4
□Method CVR		0,2	0,2
• Peer SDI		1,92	1,47
□Method SDI		1,10	1,16
• Peer CVR	2	0,3	0,3
□Method CVR		0,2	0,2
• Peer SDI		1,94	1,51
□Method SDI		1,30	1,33

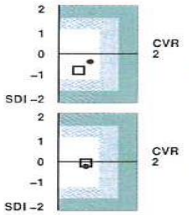


Level		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
				Abbott AEROSET/ARCHITECT (c, i, ci models)		G–glutamyl–carboxy–nitroanilide	
Mean	1	67,91	67,60	60,62	61,58	60,87	59,88
SD		1,25	1,64	3,79	4,11	6,39	6,64
CV		1,8	2,4	6,2	6,7	10,5	11,1
# Points		70	2171	2527	32132	6040	91741
# Labs				71	121	215	464
Mean	2	169,1	169,7	152,0	154,8	151,6	150,0
SD		2,72	3,22	8,79	9,93	13,37	14,76
CV		1,6	1,9	5,8	6,4	8,8	9,8
# Points		70	2170	2446	31750	5874	89855
# Labs				70	122	214	462

Glucose Hexokinase mmol/L

Abbott ARCHITECT c8000

Level		Mon	Cum
• Peer CVR	1	0,8	1,0
□Method CVR		0,5	0,7
• Peer SDI		−0,32	0,40
□Method SDI		−0,67	−0,06
• Peer CVR	2	0,7	0,8
□Method CVR		0,7	0,7
• Peer SDI		−0,19	0,50
□Method SDI		−0,05	0,60



Level		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
				Abbott AEROSET/ARCHITECT (c, i, ci models)		Hexokinase	
Mean	1	4,25	4,41	4,29	4,36	4,38	4,42
SD		0,090	0,128	0,118	0,131	0,200	0,195
CV		2,1	2,9	2,8	3,0	4,6	4,4
# Points		48	1281	3218	38772	11453	162K
# Labs				100	155	415	820
Mean	2	14,91	15,22	14,98	15,03	14,93	14,97
SD		0,270	0,299	0,391	0,390	0,416	0,424
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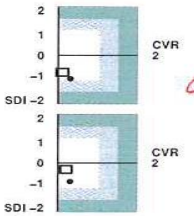
IgA Immunoturbidimetric g/L

Abbott ARCHITECT c8000

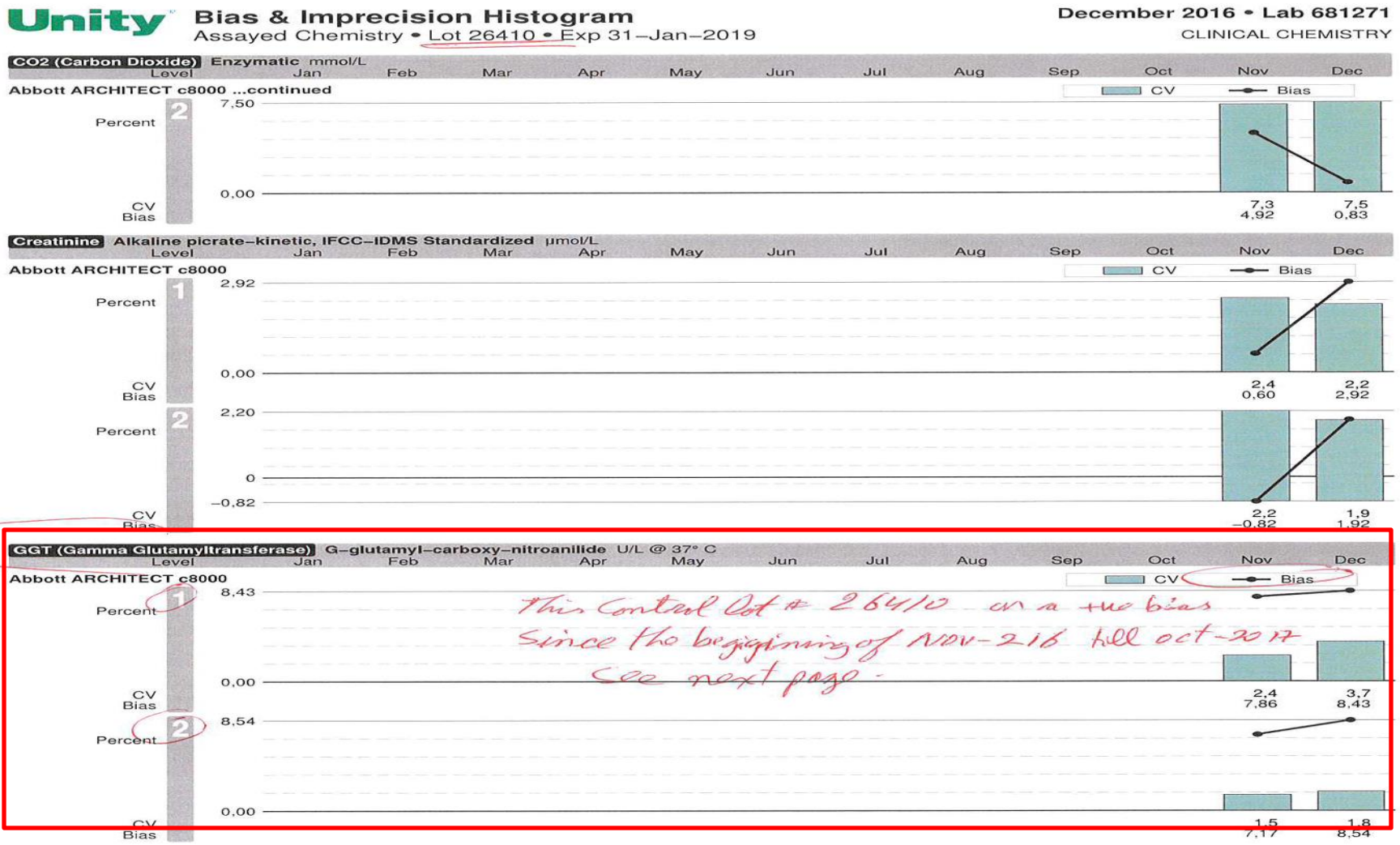
Level		Mon	Cum
• Peer CVR	1	0,3	1,3
□Method CVR		0,1	0,5
• Peer SDI		−0,96	0,23
□Method SDI		−0,70	−0,29
• Peer CVR	2	0,3	1,1
□Method CVR		0,2	0,5
• Peer SDI		−0,77	0,11
□Method SDI		−0,28	0,07



Level		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
				Abbott AEROSET/ARCHITECT (c, i, ci models)		Immunoturbidimetric	
Mean	1	1,65	1,73	1,73	1,72	1,76	1,78
SD		0,020	0,083	0,085	0,063	0,153	0,172
CV		1,2	4,8	4,9	3,7	8,7	9,6
# Points		14	490	73	2291	519	8017
# Labs				5	21	24	63
Mean	2	1,17	1,22	1,23	1,22	1,20	1,22
SD		0,020	0,053	0,080	0,046	0,096	0,103
CV		1,7	4,3	6,5	3,8	8,0	8,5
# Points		14	489	75	2275	541	7907
# Labs				6	19	26	66

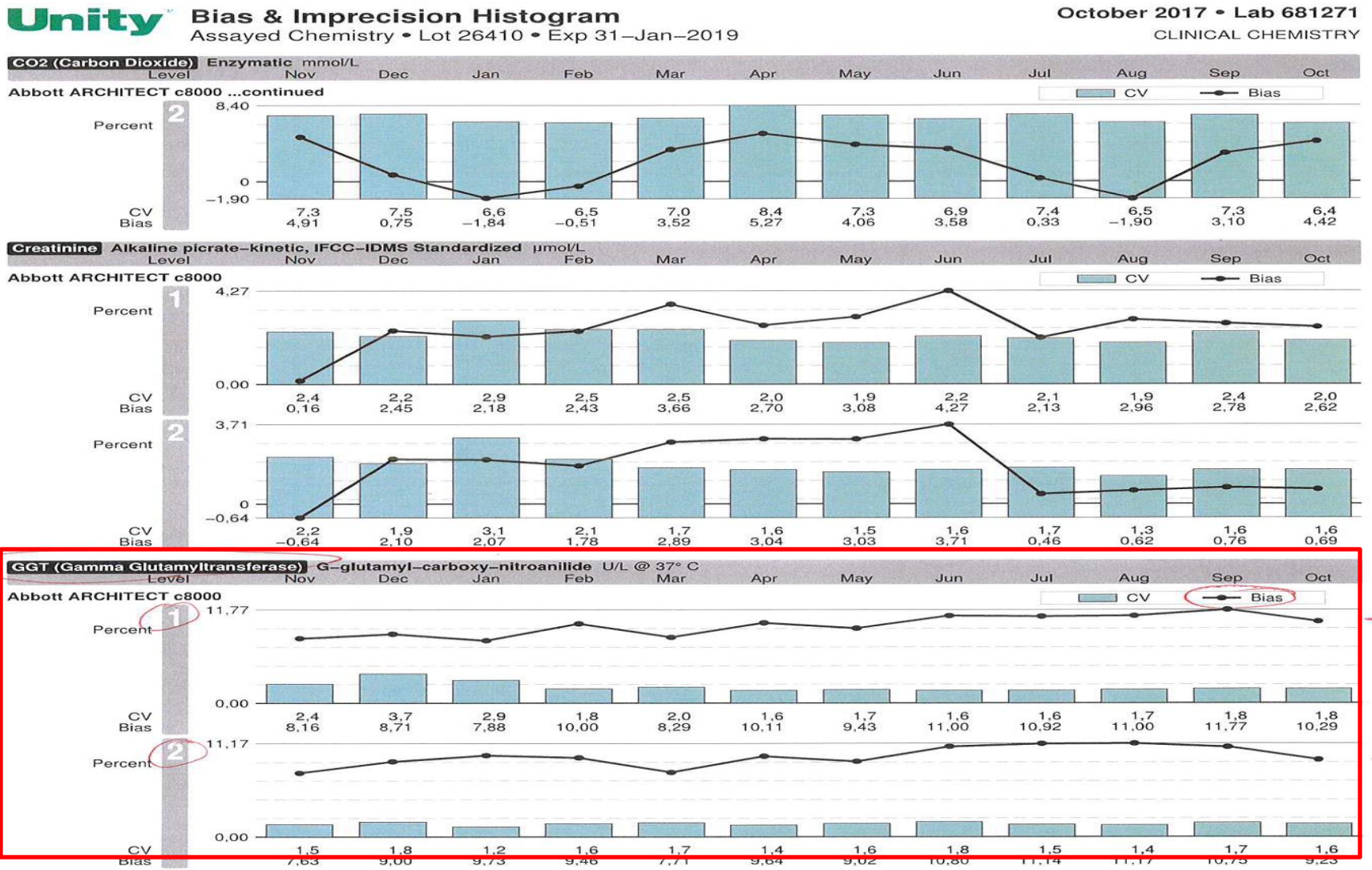
Unity "Monthly Bias & Imprecision Histogram"

GGT (December 2016)



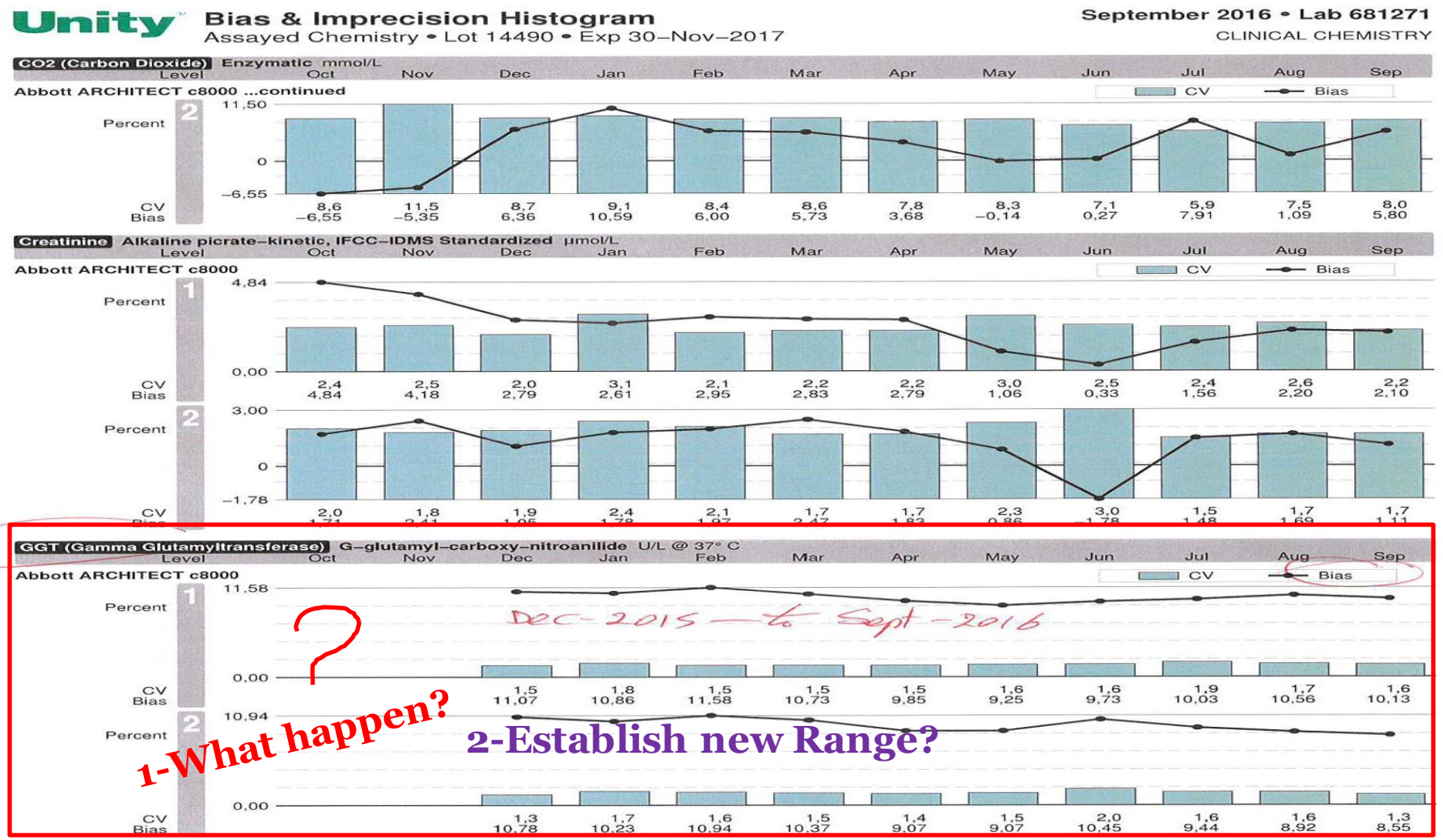
Unity "Bias & Imprecision Histogram"

GGT (October 2017)



Unity "Bias & Precision Histogram"

GGT (September 2016)



Product Information

December-2017

"Adjust the GGT calibration Factor using a standardized alignment solution."

Product Information

Received on (20-November-2017)

Date Issued September 19, 2014

Product

Product	List Number (LN)
Gamma-Glutamyl Transferase (GGT) Reagent	7D65

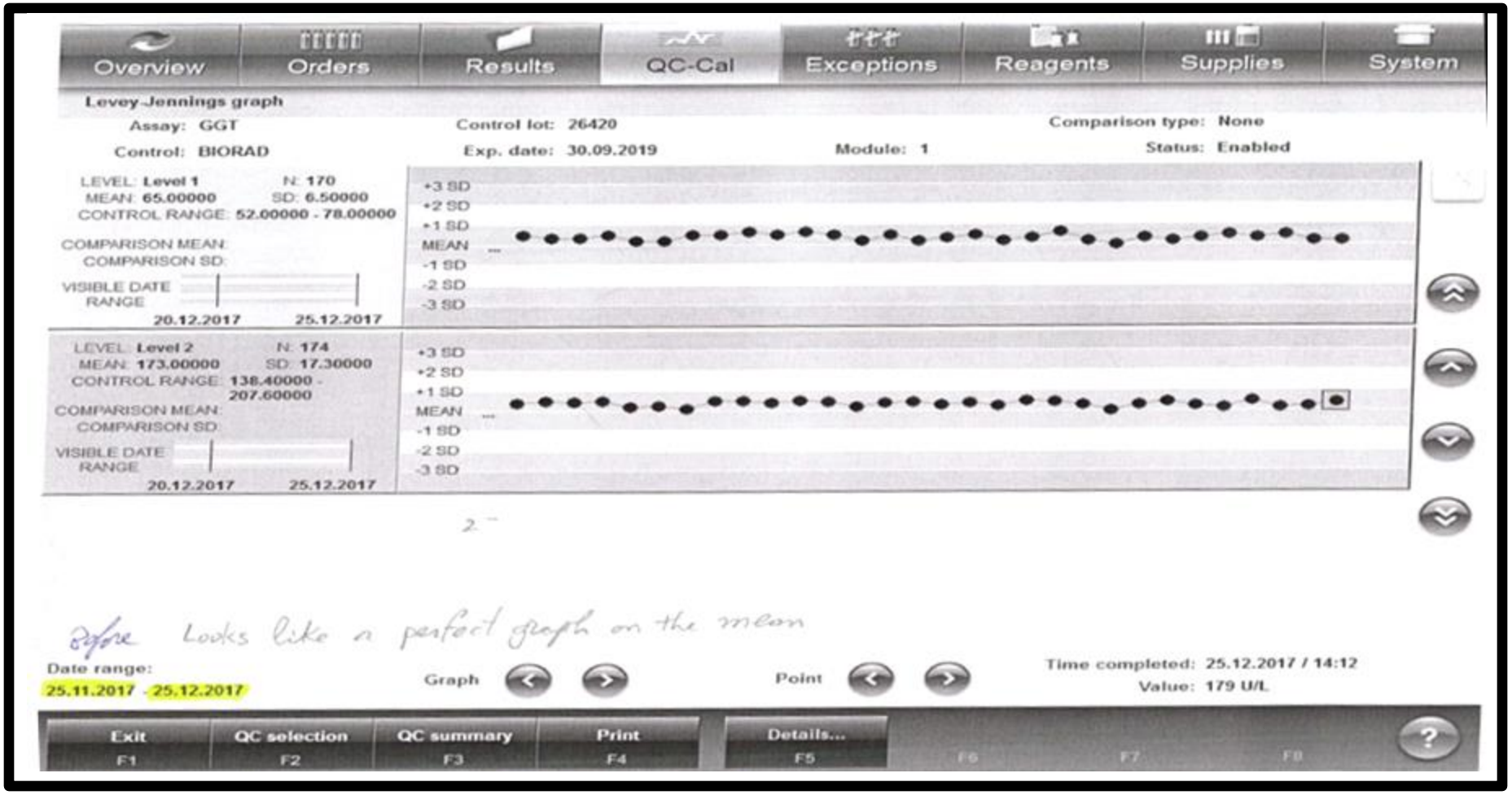
Reason

We are pleased to announce a new optional GGT alignment procedure for improved ARCHITECT *c*Systems instrument-to-instrument GGT assay results. This procedure adjusts the GGT calibration factor using a standardized alignment solution and will be available 4th quarter 2014. The procedure provides:

- Better alignment of multiple instruments within a single laboratory
- Better agreement between laboratories across a network

The disadvantage of not having a means of comparing your Q.C results with your Peer group, example Unity.

Levy Jennings chart from Instrument looks perfect. **Before changing the factor.**



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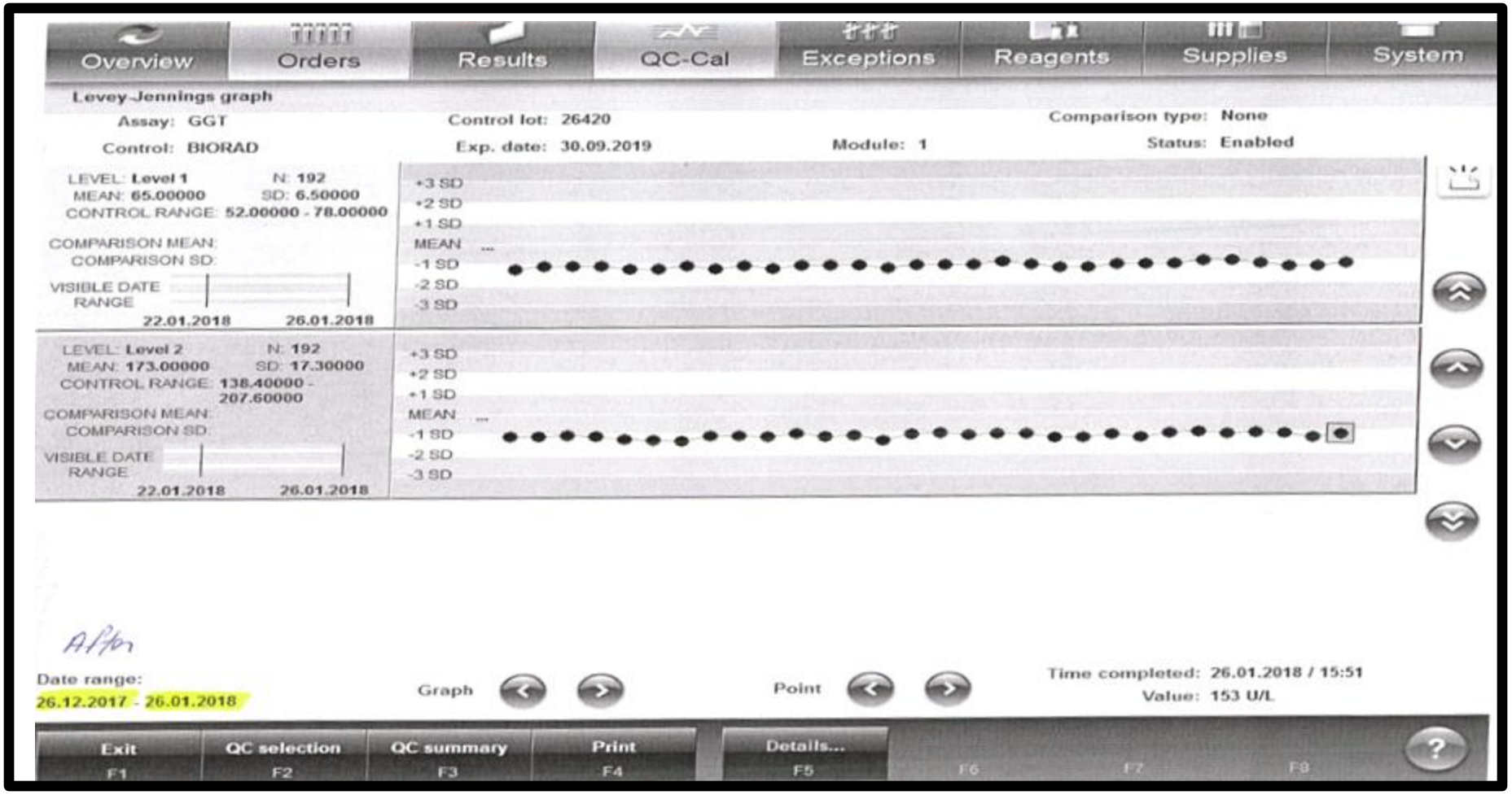
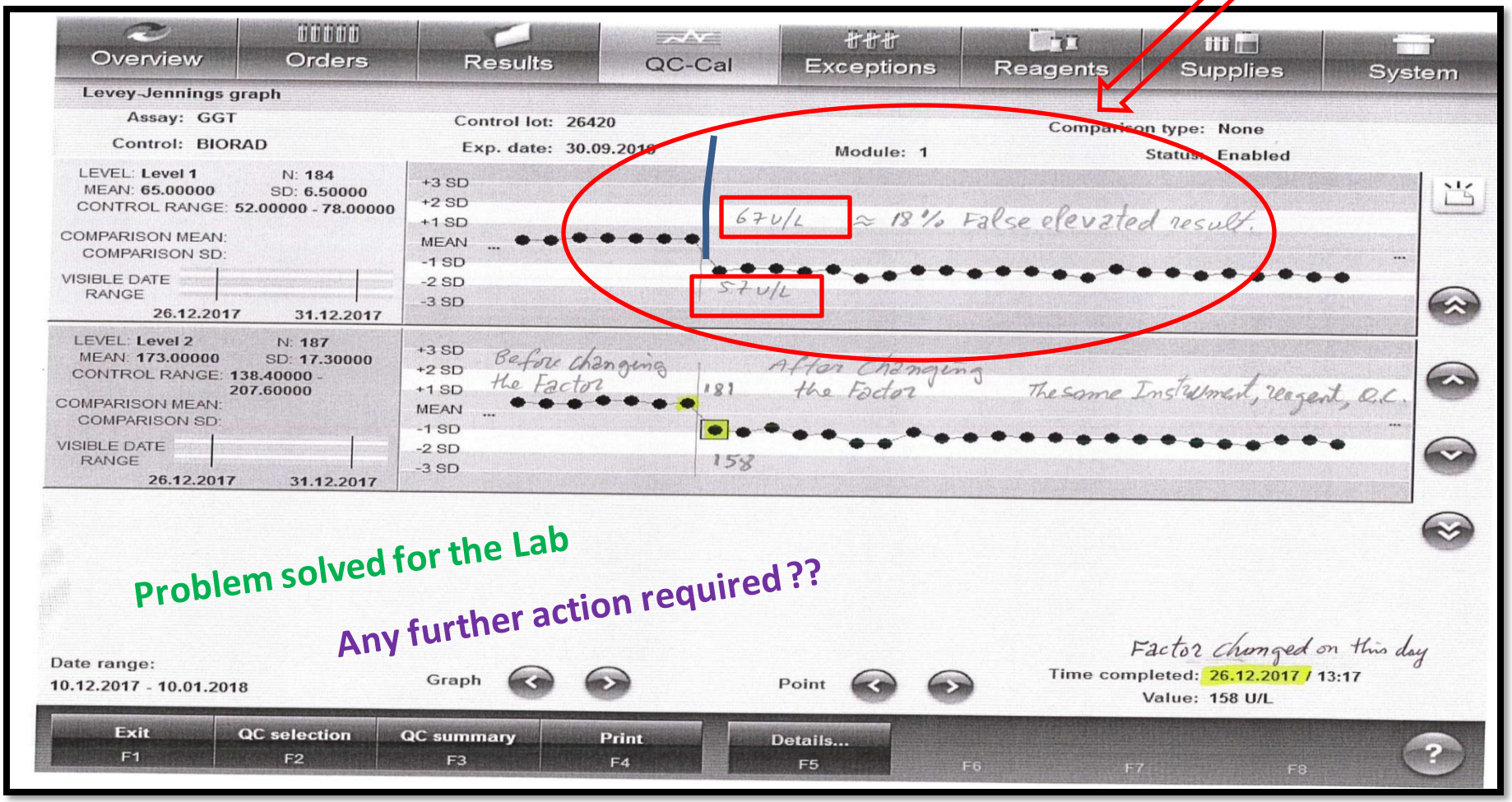


The Advantage of having a means of comparing your Q.C with your Peer group, example Unity.

Factor changed on this day, (26-12-2017).

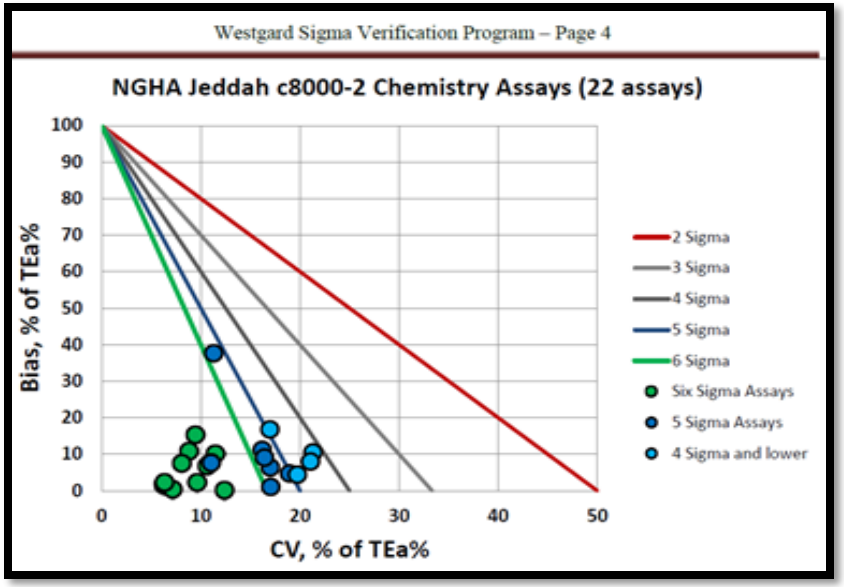
Readings of the same control Before and after the Factor change showing an 18% falsely elevated result.

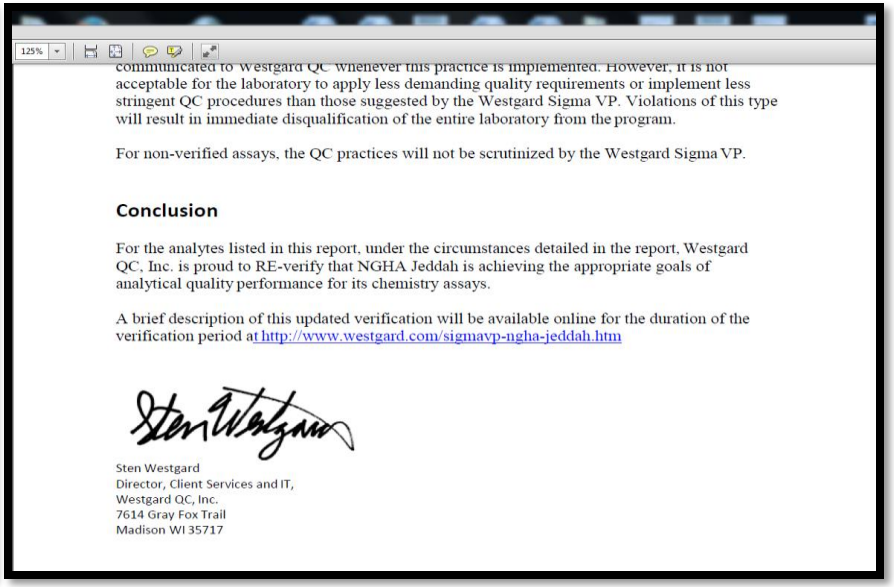
Which explains the years of continuous +ve bias for Q.C as well as patient result.



No patient harm was done.

GGT showed a Marginal performance, but with in 2 S.D.





communicated to Westgard QC whenever this practice is implemented. However, it is not acceptable for the laboratory to apply less demanding quality requirements or implement less stringent QC procedures than those suggested by the Westgard Sigma VP. Violations of this type will result in immediate disqualification of the entire laboratory from the program.

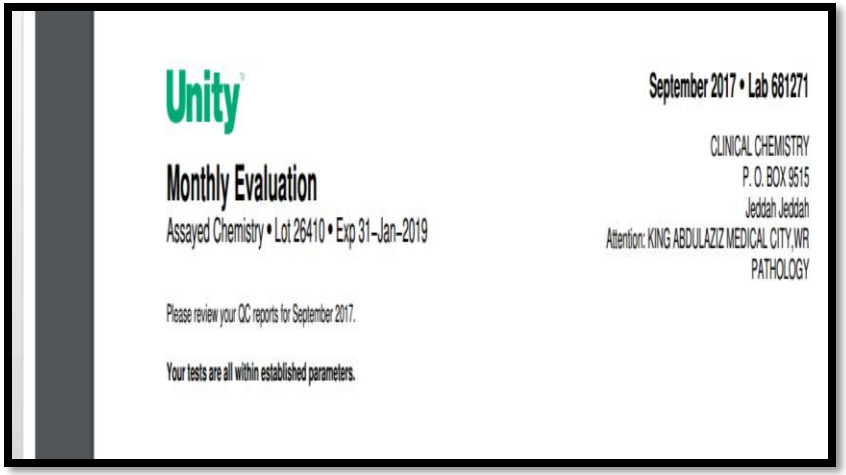
For non-verified assays, the QC practices will not be scrutinized by the Westgard Sigma VP.

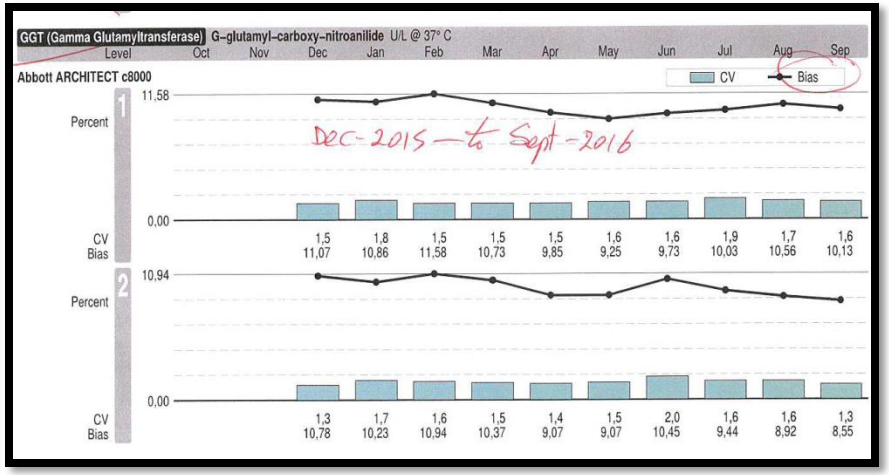
Conclusion

For the analytes listed in this report, under the circumstances detailed in the report, Westgard QC, Inc. is proud to RE-verify that NGHA Jeddah is achieving the appropriate goals of analytical quality performance for its chemistry assays.

A brief description of this updated verification will be available online for the duration of the verification period at http://www.westgard.com/sigmavp-ngha-jeddah.htm

Sten Westgard
Director, Client Services and IT,
Westgard QC, Inc.
7614 Gray Fox Trail
Madison WI 35717





The magnitude of Risk

If there was no Peer comparison

The direct effect of all that to the patient

Work Load Statistics of GGT from 2014 to 2017

Year	source of data	# of Samples
2014	Estimate	70,000
2015	Estimate	70,000
2016	CERNER	115,601
2017	CERNER	73,741
Total		**329,342**

Number of Patients at 3.3 samples per patient (source) AinIQ-BIS

99,800 = 100,000 patients since 2014 in Jeddah only

1

2

3

? # of Patients

Cost of Good Quality Vs **Cost of Poor Quality**

1 vial per 3 days, 1 kit =12 vials = SAR 1000

1 kit of Q.C-1 & Q.C-2, 2 kits per month = SAR 2000

In 3 Years 2000 x 36 = **SAR 72,000 ($ 19,200)**

SAR 100,000,000
($26,666,666)

Cost of Quality

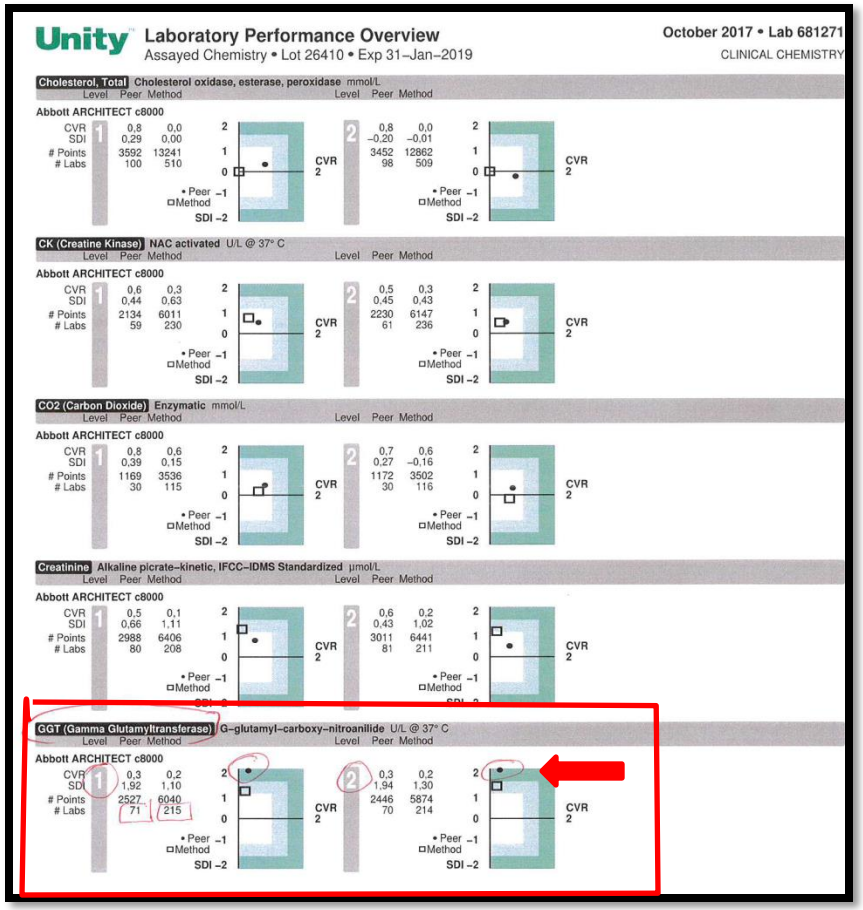
- CLSI Report QMS20-R. 2014 (understanding the cost of Quality in the Laboratory)

- Cost of Quality for Return on Investment (ROI)
- Cost of Good Quality (prevention/appraisal/upfront cost)
- Cost of Poor Quality (internal failure/external failure cost)
- Hard cost vs soft cost
- Cost saving Vs cost avoidance , templates/Forms/Charts

- $$R.O.I = \frac{(\text{Amount Gained} - \text{Amount spent})}{\text{Amount Spent}} \times 100$$

Laboratory Performance Overview (GGT)

Before changing the Factor



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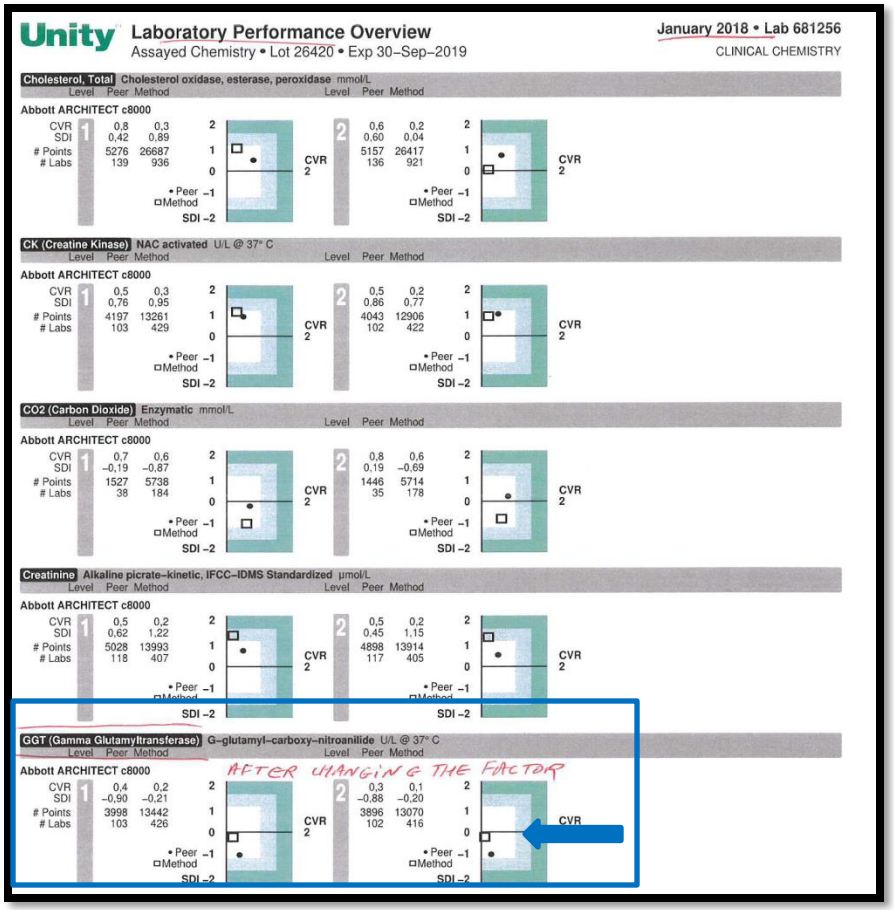
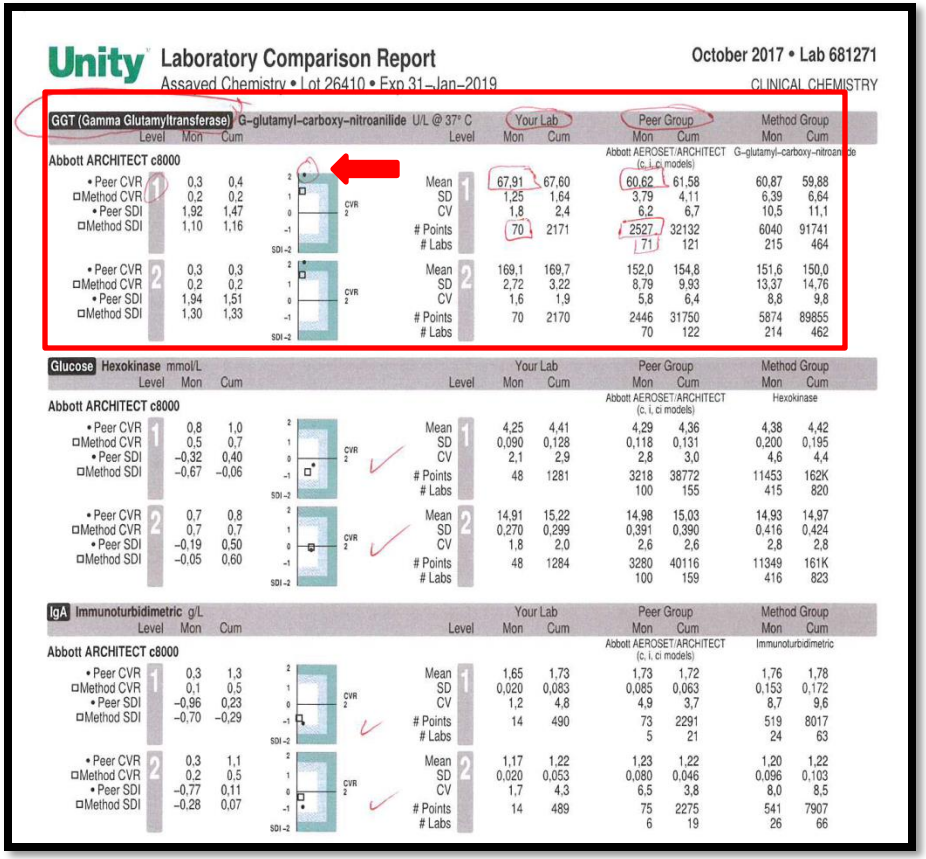


Laboratory Comparison Report (GGT)

Before changing the Factor



Unity Laboratory Comparison Report

Assayed Chemistry • Lot 26410 • Exp 31-Jan-2019

October 2017 • Lab 681271

CLINICAL CHEMISTRY

GGT (Gamma Glutamyltransferase) G-glutamyl-carboxy-nitroanilide U/L @ 37° C

Abbott ARCHITECT c8000

Level		Mon	Cum		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
							Abbott AEROSET/ARCHITECT (c, i, ci models)		G-glutamyl-carboxy-nitroanilide	
1	• Peer CVR	0,3	0,4	Mean	67,91	67,60	60,62	61,58	60,87	59,88
	□Method CVR	0,2	0,2	SD	1,25	1,64	3,79	4,11	6,39	6,64
	• Peer SDI	1,92	1,47	CV	1,8	2,4	6,2	6,7	10,5	11,1
	□Method SDI	1,10	1,16	# Points	70	2171	2527	32132	6040	91741
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				# Labs			70	122	214	462

Glucose Hexokinase mmol/L

Abbott ARCHITECT c8000

Level		Mon	Cum		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
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1	• Peer CVR	0,8	1,0	Mean	4,25	4,41	4,29	4,36	4,38	4,42
	□Method CVR	0,5	0,7	SD	0,090	0,128	0,118	0,131	0,200	0,195
	• Peer SDI	−0,32	0,40	CV	2,1	2,9	2,8	3,0	4,6	4,4
	□Method SDI	−0,67	−0,06	# Points	48	1281	3218	38772	11453	162K
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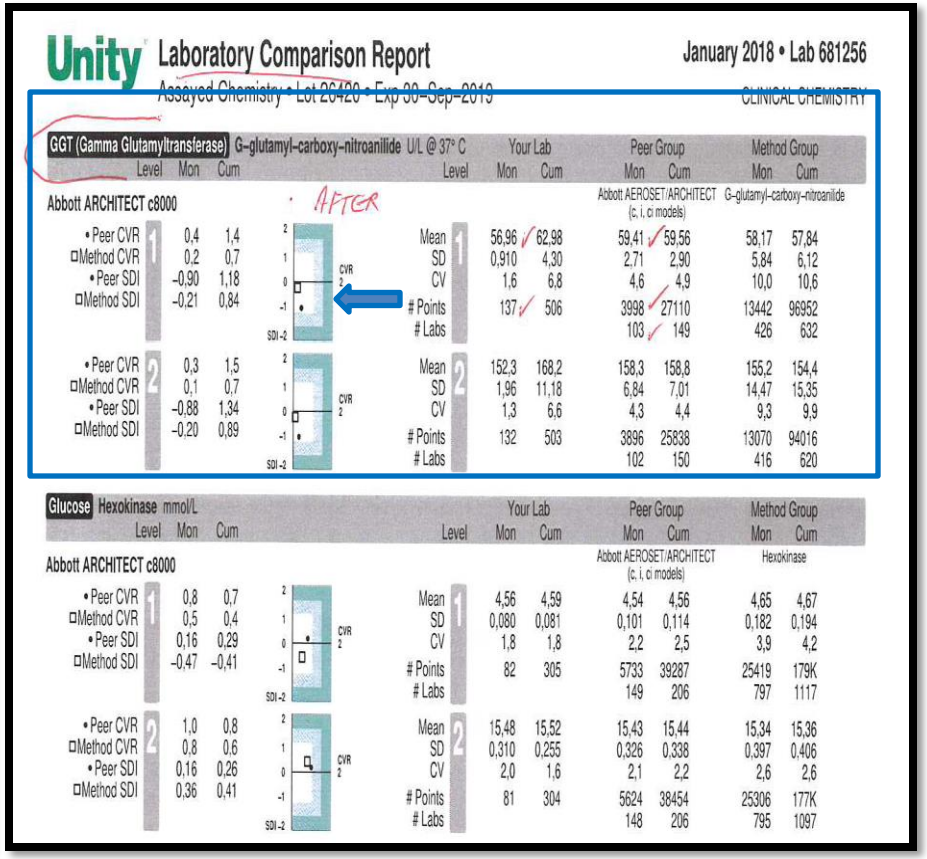
1	• Peer CVR	0,3	1,3	Mean	1,65	1,73	1,73	1,72	1,76	1,78
	□Method CVR	0,1	0,5	SD	0,020	0,083	0,085	0,063	0,153	0,172
	• Peer SDI	−0,96	0,23	CV	1,2	4,8	4,9	3,7	8,7	9,6
	□Method SDI	−0,70	−0,29	# Points	14	490	73	2291	519	8017
				# Labs			5	21	24	63
2	• Peer CVR	0,3	1,1	Mean	1,17	1,22	1,23	1,22	1,20	1,22
	□Method CVR	0,2	0,5	SD	0,020	0,053	0,080	0,046	0,096	0,103
	• Peer SDI	−0,77	0,11	CV	1,7	4,3	6,5	3,8	8,0	8,5
	□Method SDI	−0,28	0,07	# Points	14	489	75	2275	541	7907
				# Labs			6	19	26	66

After changing the Factor



Unity Laboratory Comparison Report

Assayed Chemistry • Lot 26420 • Exp 30-Sep-2019

January 2018 • Lab 681256

CLINICAL CHEMISTRY

GGT (Gamma Glutamyltransferase) G-glutamyl-carboxy-nitroanilide U/L @ 37° C

Abbott ARCHITECT c8000

AFTER

Level		Mon	Cum		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
							Abbott AEROSET/ARCHITECT (c, i, ci models)		G-glutamyl-carboxy-nitroanilide	
1	• Peer CVR	0,4	1,4	Mean	56,96	62,98	59,41	59,56	58,17	57,84
	□Method CVR	0,2	0,7	SD	0,910	4,30	2,71	2,90	5,84	6,12
	• Peer SDI	−0,90	1,18	CV	1,6	6,8	4,6	4,9	10,0	10,6
	□Method SDI	−0,21	0,84	# Points	137	506	3998	27110	13442	96952
				# Labs			103	149	426	632
2	• Peer CVR	0,3	1,5	Mean	152,3	168,2	158,3	158,8	155,2	154,4
	□Method CVR	0,1	0,7	SD	1,96	11,18	6,84	7,01	14,47	15,35
	• Peer SDI	−0,88	1,34	CV	1,3	6,6	4,3	4,4	9,3	9,9
	□Method SDI	−0,20	0,89	# Points	132	503	3896	25838	13070	94016
				# Labs			102	150	416	620

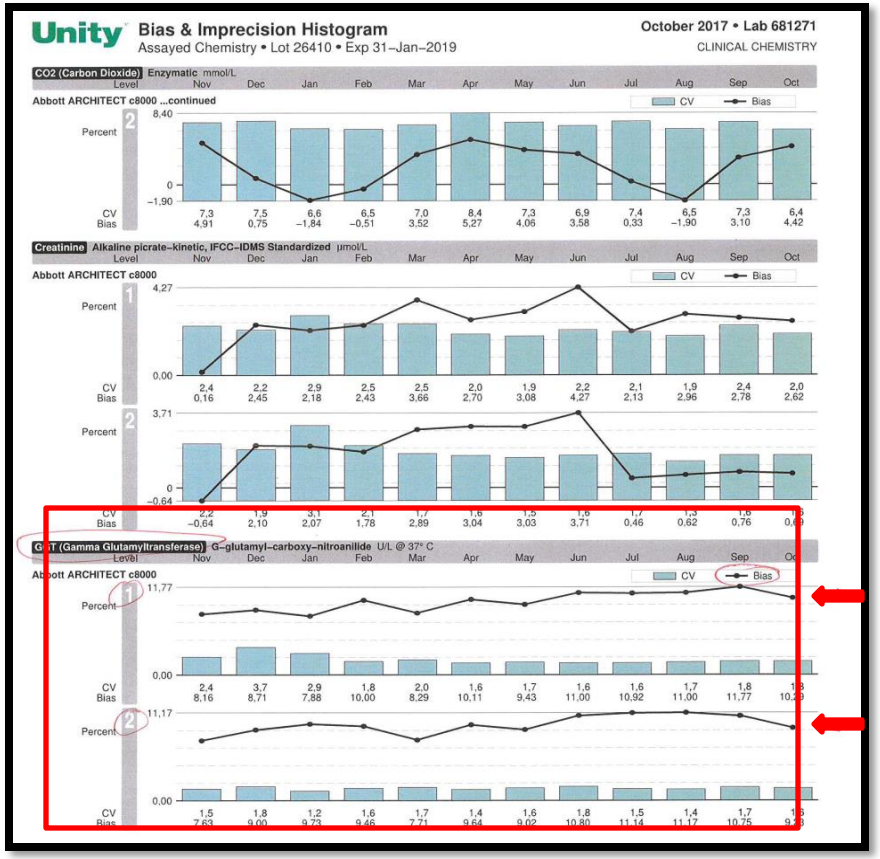
Glucose Hexokinase mmol/L

Abbott ARCHITECT c8000

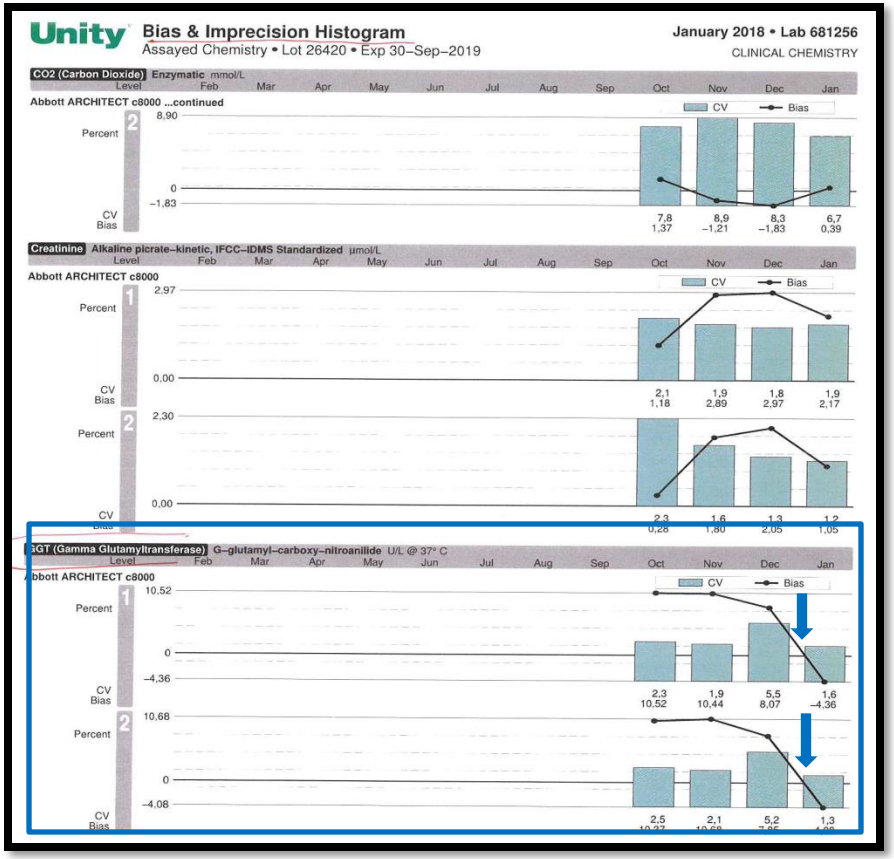
Level		Mon	Cum		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
							Abbott AEROSET/ARCHITECT (c, i, ci models)		Hexokinase	
1	• Peer CVR	0,8	0,7	Mean	4,56	4,59	4,54	4,56	4,65	4,67
	□Method CVR	0,5	0,4	SD	0,080	0,081	0,101	0,114	0,182	0,194
	• Peer SDI	0,16	0,29	CV	1,8	1,8	2,2	2,5	3,9	4,2
	□Method SDI	−0,47	−0,41	# Points	82	305	5733	39287	25419	179K
				# Labs			149	206	797	1117
2	• Peer CVR	1,0	0,8	Mean	15,48	15,52	15,43	15,44	15,34	15,36
	□Method CVR	0,8	0,6	SD	0,310	0,255	0,326	0,338	0,397	0,406
	• Peer SDI	0,16	0,26	CV	2,0	1,6	2,1	2,2	2,6	2,6
	□Method SDI	0,36	0,41	# Points	81	304	5624	38454	25306	177K
				# Labs			148	206	795	1097

Bias imprecision (GGT)

Before changing the Factor



After changing the Factor



Learning from mistakes (GGT)

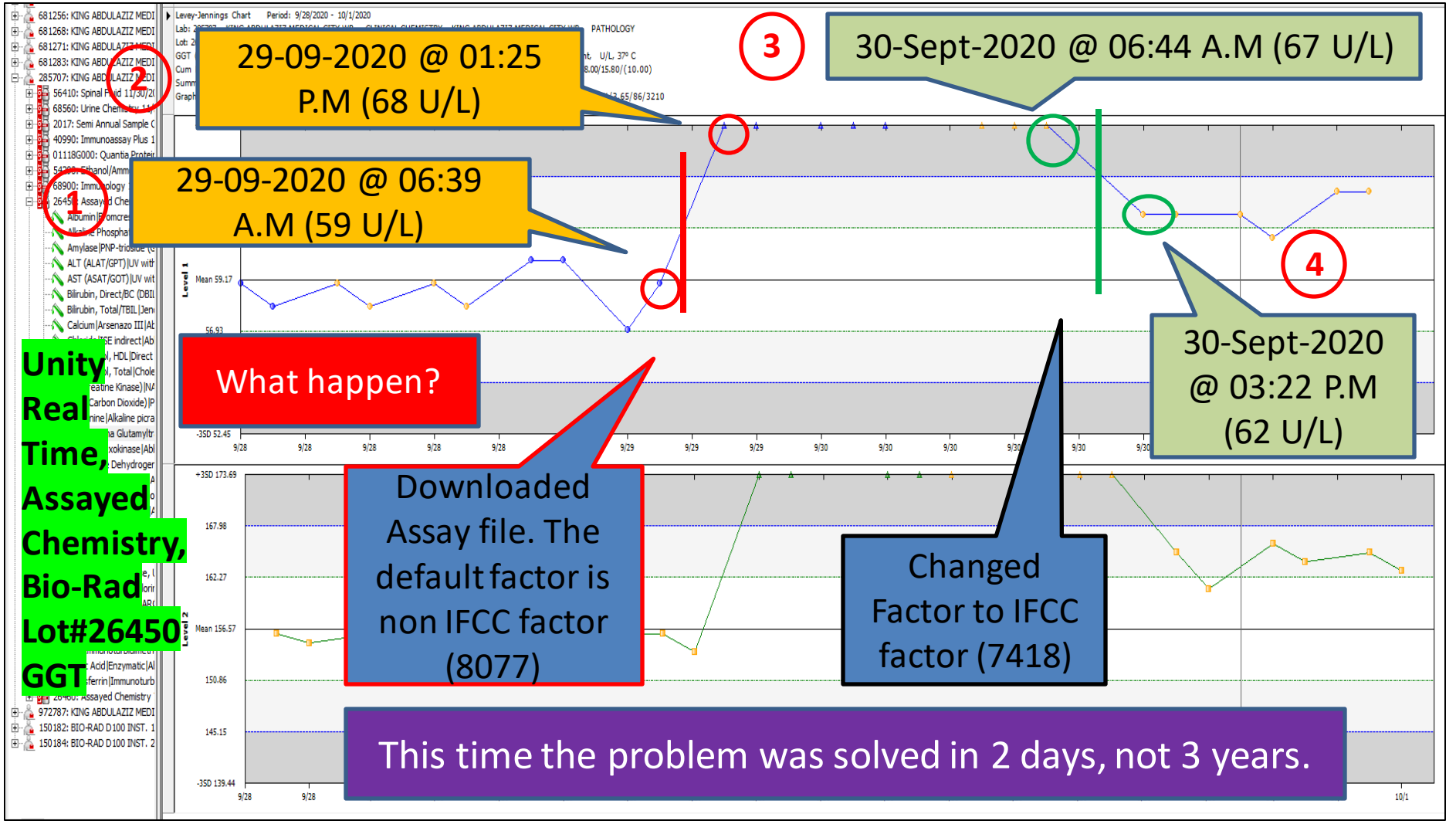
What are the chances of this will:

1. Happen to your Lab?

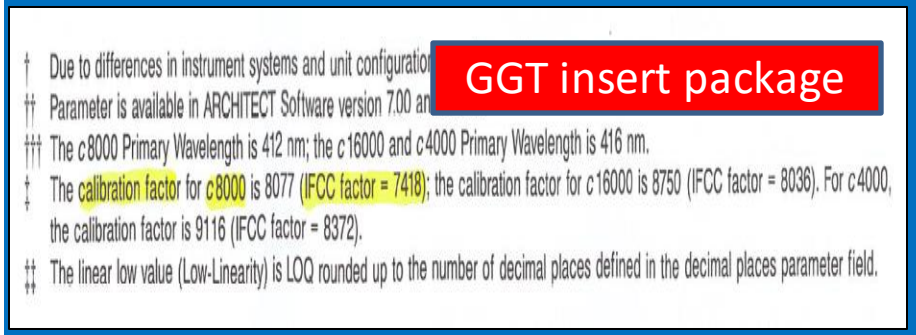
   or

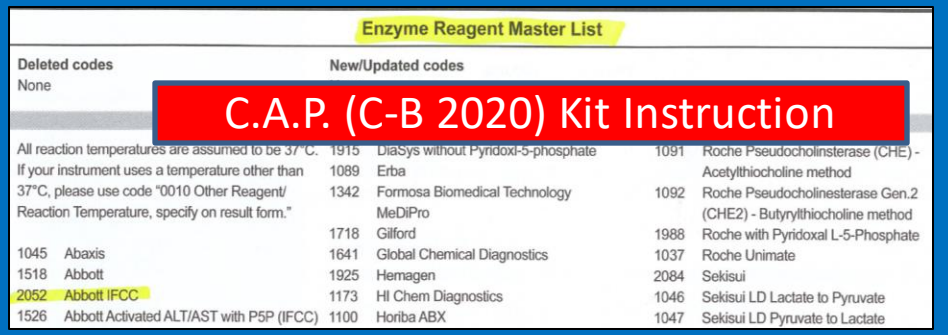
2. Happen to our Lab again?

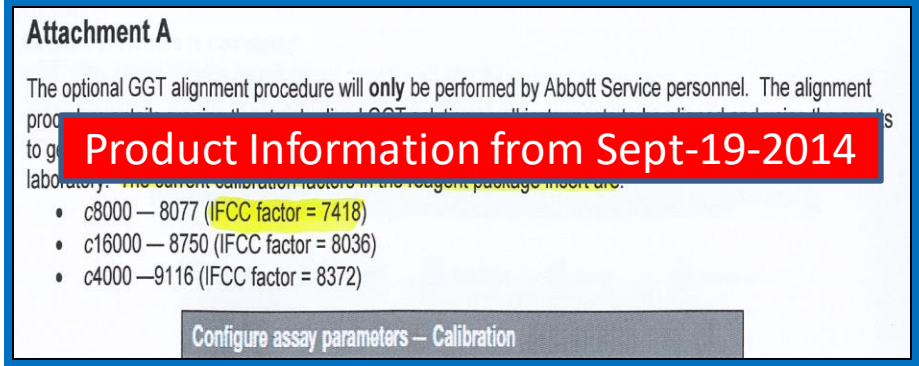
Second wave of GGT +ve bias after 2 years and 9 months (29-Sept-2020)

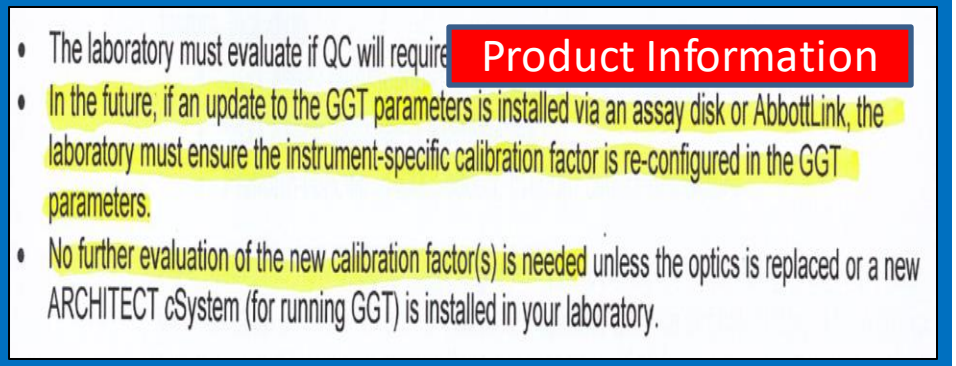


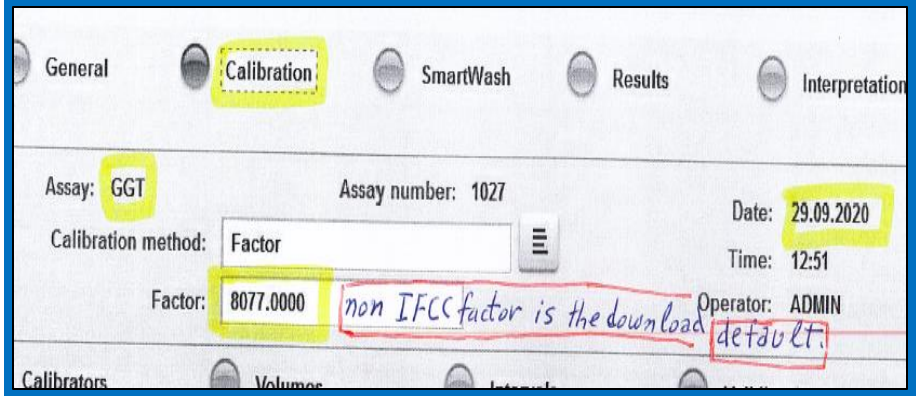
Why IFCC factor?

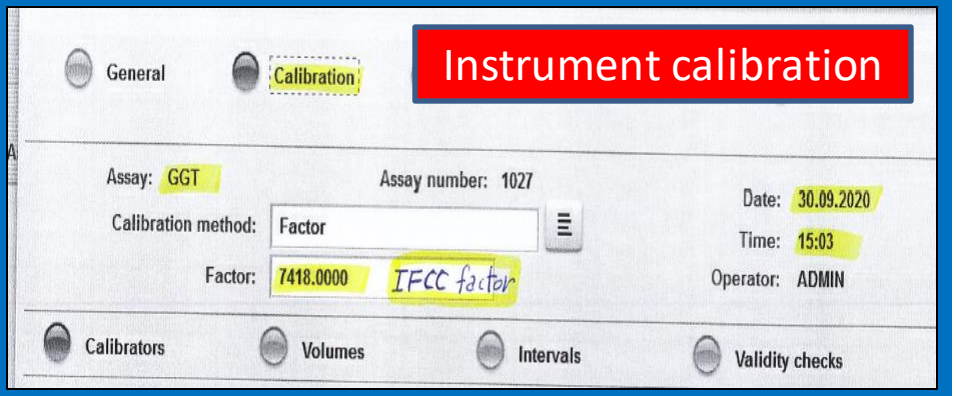












Summary

1- Case # 1 (GGT)

- Unity Monthly Report showed marginal Performance. (Continuous Positive bias)

- Investigation - vendor Product Information Letter recommended Adjust Calibration Factor.

- Calibrator Adjusted – Problem Solved.
- Second wave of GGT + ve bias, (29-Sept-2020)

Case study # 2

Vancomycin

Feb-2018, Pharmacy called the Lab.

You are giving us….

"higher results than expected of Vancomycin trough levels."

Checked Q.C results on Instruments

Checked Q.C results and Q.C History on Unity (www.QCNet.com)

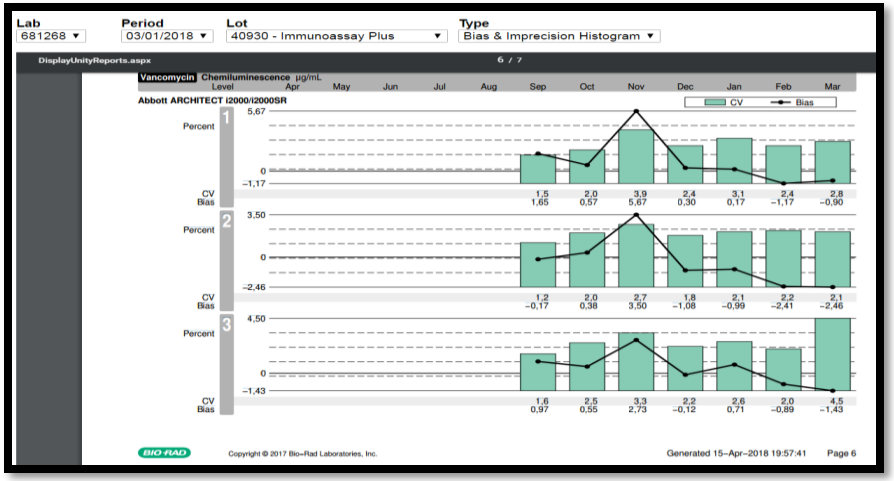
Checked recent C.A.P. surveys

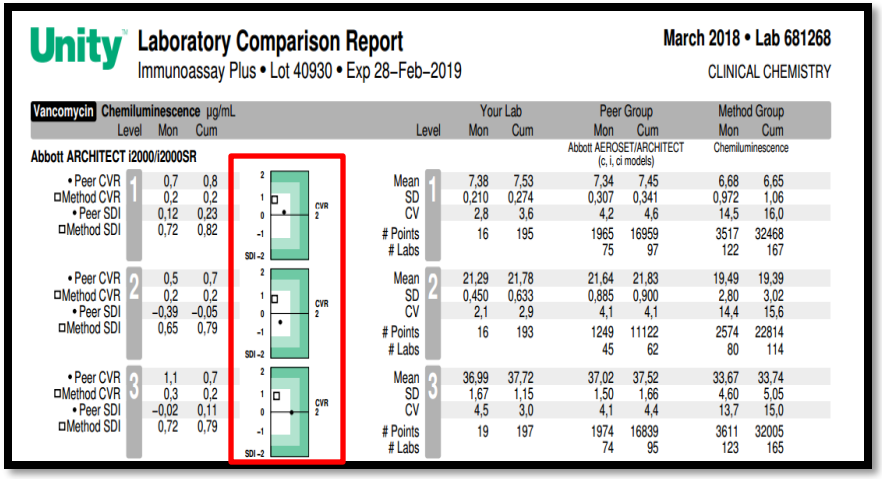
Our Controls are good compared to our Peers.

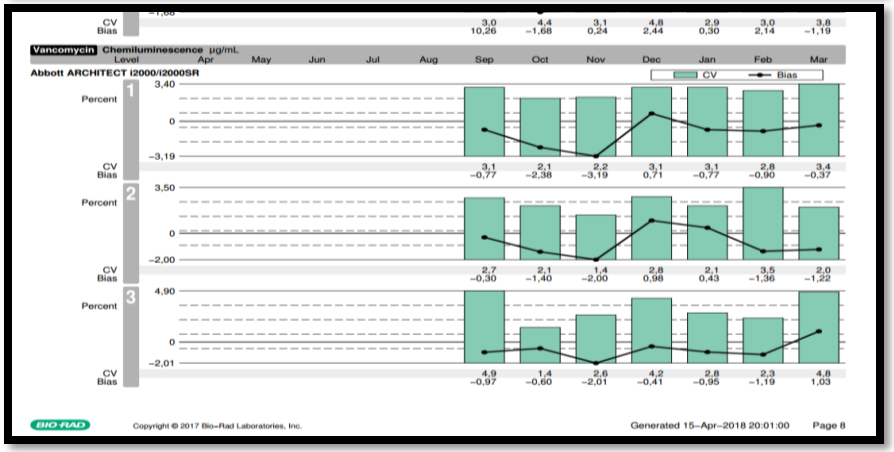
Case study # 2 — Vancomycin — Pre-analytical

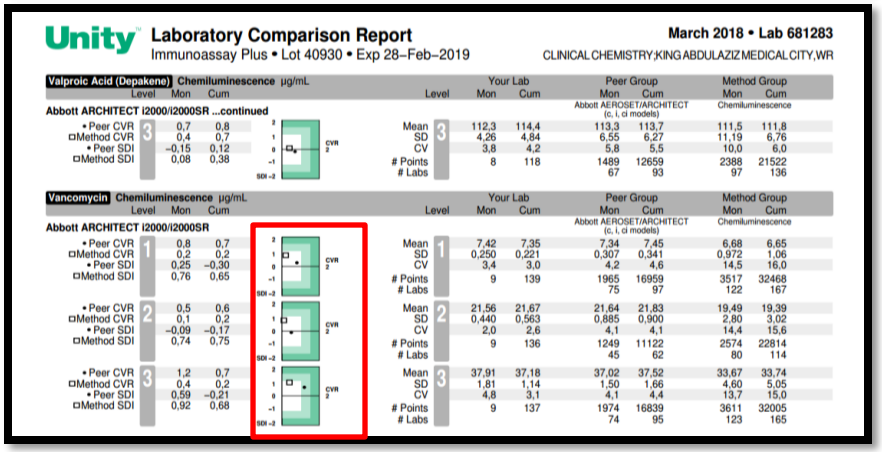
Feb-2018, Pharmacy, higher results than expected since November-2017

- Two Instruments performance with Quality Control Material. **(Peers = 75 Labs, Method = 122 Labs)**







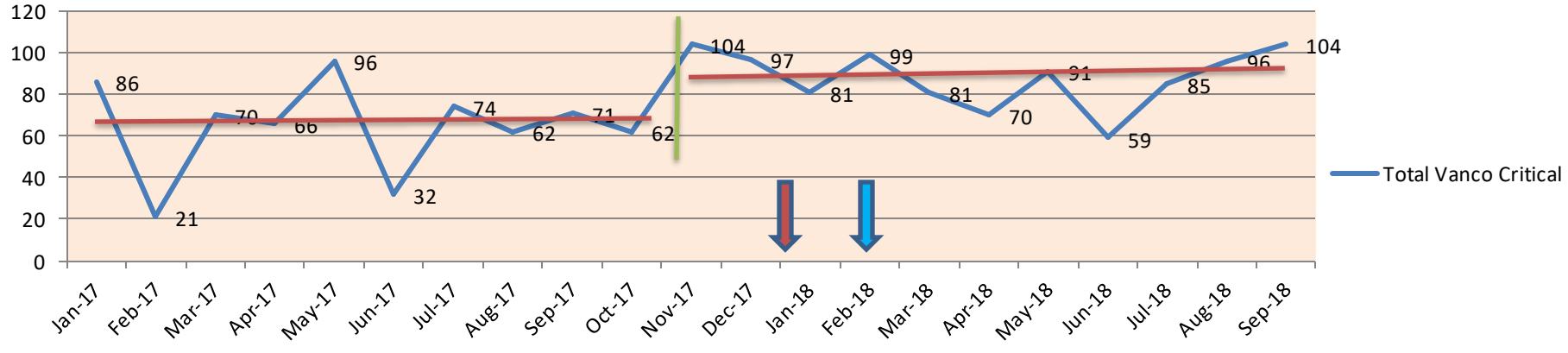


Case study # 2 — Vancomycin — Preanalytical

Feb-2018, Pharmacy, higher results than expected since November-2017

- Two Instruments performance with patient samples in the past Two years.

Total numbers of Vancomycin Critical results (Greater than 20.99 ug/ml), phoned to the physician (Jan 2017 to Sept 2018)



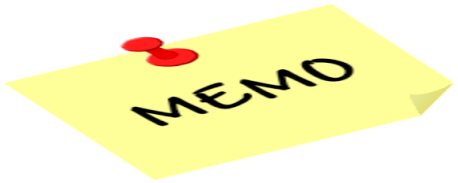
Conclusion

- No further Investigation in Analytical phase.
- Investigate Pre-Pre-Analytical. (Pharmacy)
- "Up to 75% of Lab errors occur in pre-analytical phase." ??

What happen ?

Why this Example ?

Case study # 2 — Vancomycin — Preanalytical



Feb-2018, Pharmacy, higher results than expected.

Pre-Pre-Analytical Investigation

Summary

2- Case # 2 (Vancomycine)

- Pharmacy queried "Vancomycin trough results lately higher than expected."

- Unity Monthly Report showed Good Q.C Performance compared with Peer group. (Peer/Method = 75/122 Labs) (confidence)

- No further Investigation in Analytical Phase.

- Origin of Problem was found to be Pre-Pre-Analytical. (Medication)

Case study # 3 Micro albumin/Urine Albumin Calibrator

19-02-2019, Unity Real Time (Monthly Evaluation Report)

Urine Chemistry Control lot # 66800 Exp. Date 31-03-2019

- Two levels of control outside the acceptable Peer 2 SDI. compared to 69 Laboratories Globally (2434 points).
- Two Instruments

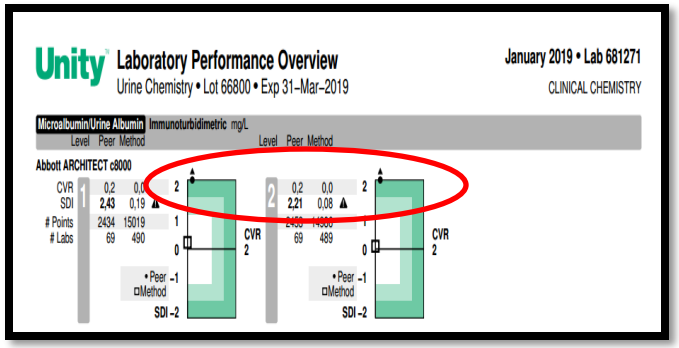
Case study # 3 Micro albumin/Urine Albumin Calibrator

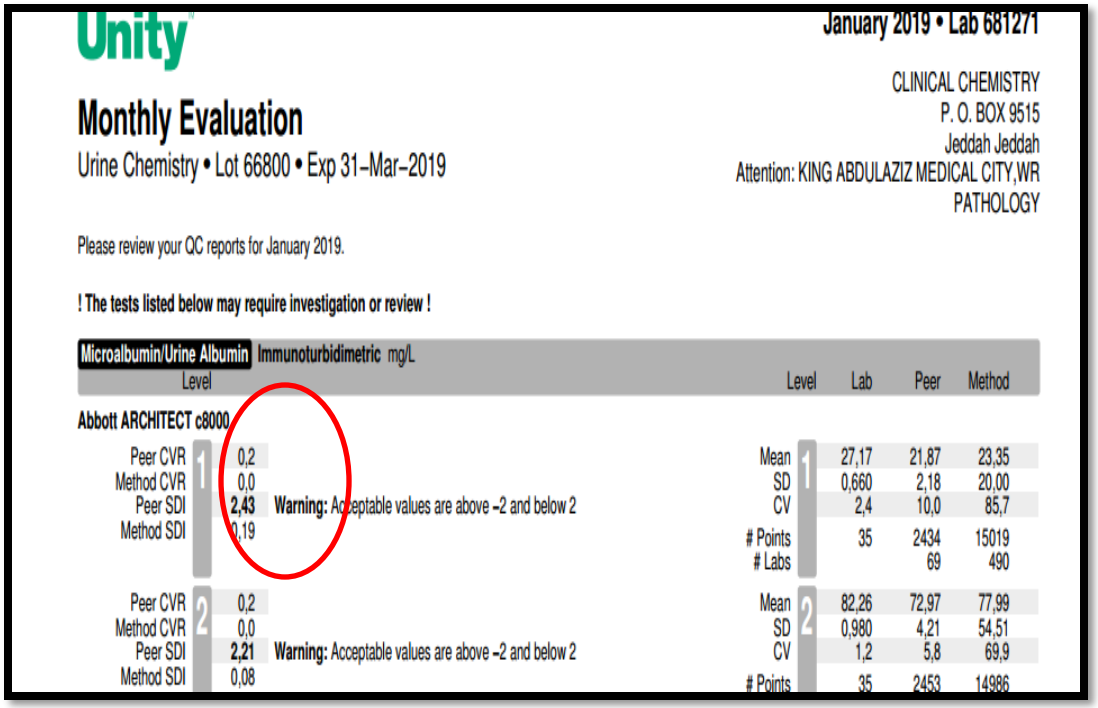
Micro albumin/Urine Albumin

19-02-2019, Unity Real Time (Monthly Evaluation Report)

Finding/Problem

- **Urine Chemistry Control lot # 66800 Exp. Date 31-03-2019**
- **Two levels of control out side the acceptable Peer 2 SDI, compared to 69 Laboratories Globally (2434 points), on Two Instruments.**





Case study # 3 Micro albumin/Urine Albumin Calibrator

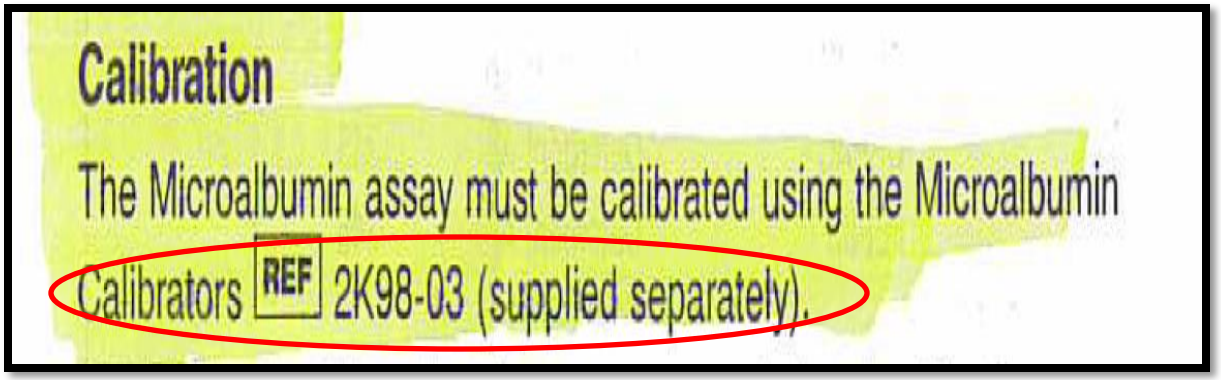
Micro albumin/Urine Albumin

19-02-2019, Unity Real Time (Monthly Evaluation Report)

Urine Chemistry Control lot # 66800 Exp. Date 31-03-2019

Investigation

- **Current in use Micro albumin calibrator (Ref. # 2K98-02)**
- **Insert package for Micro albumin reagent**
- **Under Calibration paragraph:- "The Microalbumin assay must be calibrated using the microalbumin calibrator ref # 2K98-03"**



Case study # 3 Micro albumin/Urine Albumin Calibrator

Micro albumin/Urine Albumin

19-02-2019, Unity Real Time (Monthly Evaluation Report)

Urine Chemistry Control lot # 66800 Exp. Date 31-03-2019

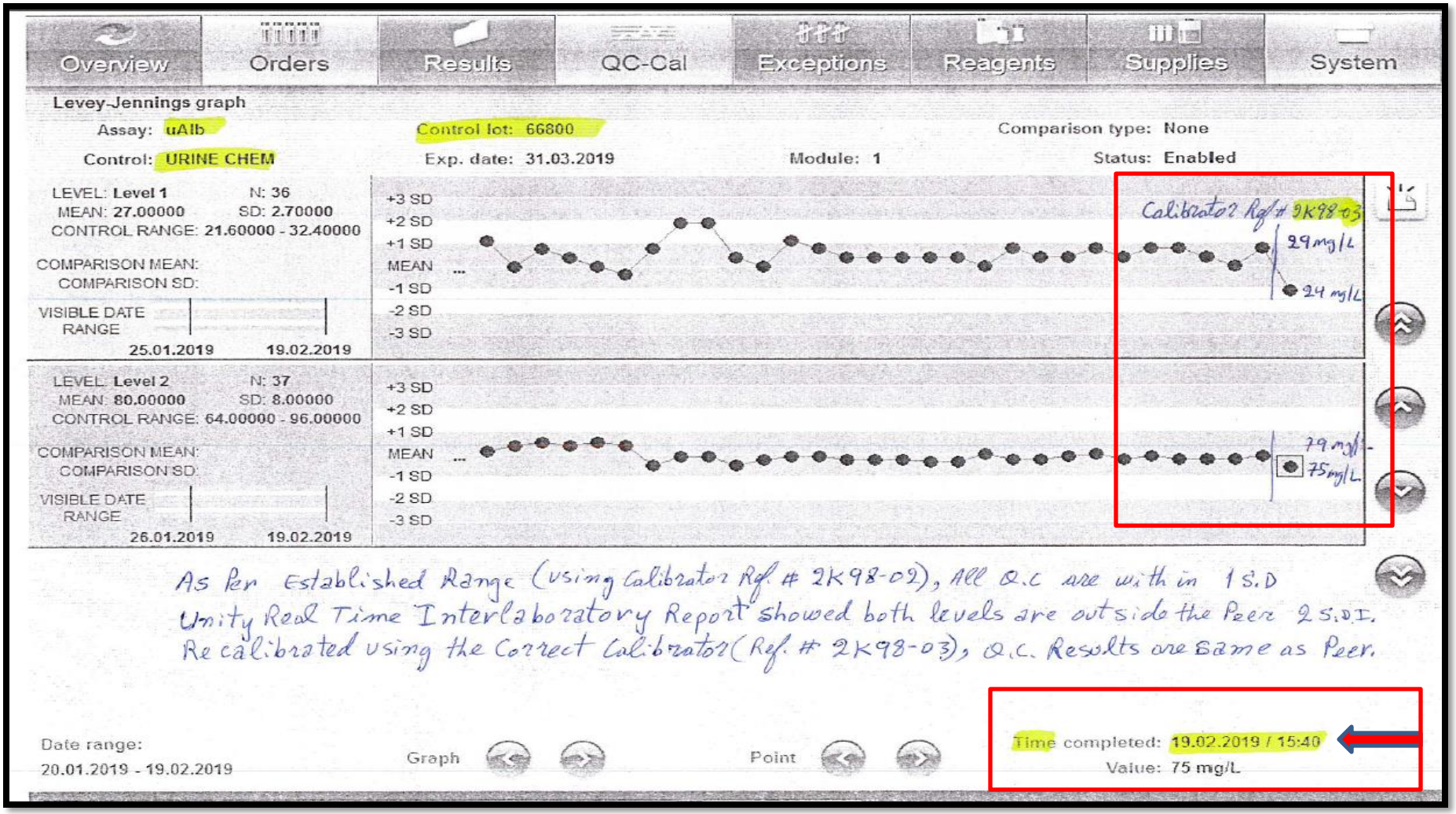
Solution

- **Recalibrated both Instruments with the correct calibrator and run the same control. Result the same as the peer value. See Levy-Jennings graph print out.**

Case study # 3 Micro albumin calibrator

Micro albumin/Urine Albumin

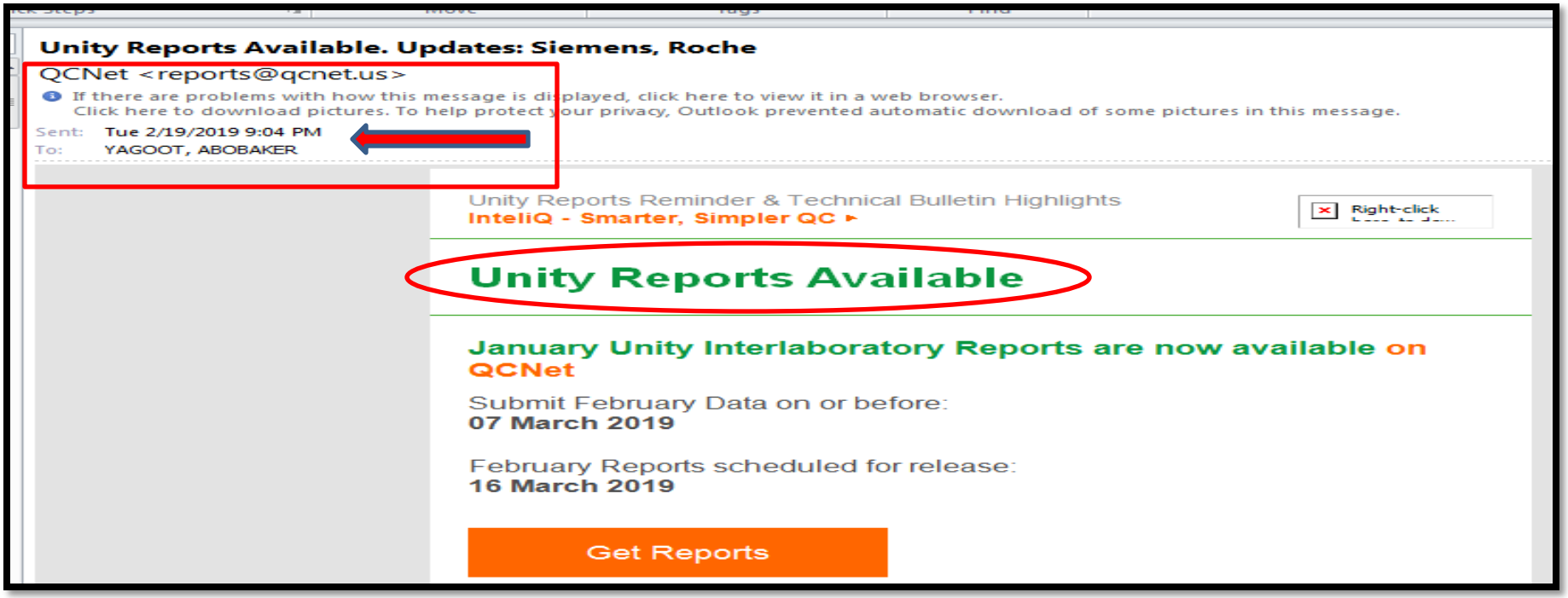
Levy Jennings graph – Instrument print out



Case study # 3 Micro albumin calibrator

Micro albumin/Urine Albumin

- **Bio-Rad Notification. Unity Report Available in QCNet.**



- E-mail from Bio-Rad on Feb-19-2019 **@ 9:04 PM**, opened on 20-02-2019
- Investigation done and problem solved for Two instruments 19-02-2019 **@ 3:40 PM**
- How was the Lab able to do that**???**
- (Unity Monthly Report printed on 17-Feb-2019 @18:07:51)

Why this Example ?

Summary

3- Case # 3 (Microalbumin / Urine Albumin)

- Unity Report for January 2019:
  Both the two Controls for the two Instruments outside the Peer range.

- Investigation – As per Reagent Insert Package – needed different version of calibrator than the one in use.

- Calibrated – Problem solved.

Case study # 4 Free T3 New 6 point calibrator

Product Information on (September-10-2019)

New assay file, new reagent , new calibrator (6 point)

Immediately after starting the new calibrator:

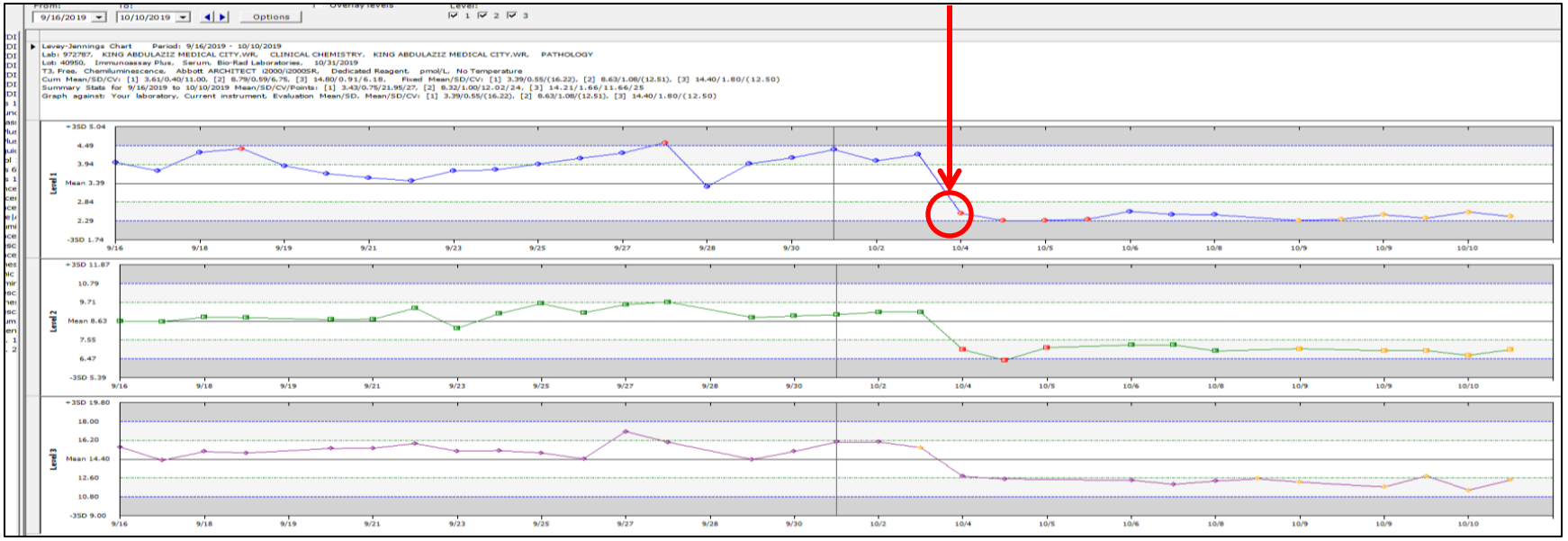
- Bio-Rad Q.C results were low outside the manufacturer range for Two different lot #s.
- The Two lots of Independent control picked up the problem
- Single / Company Q.C all level on a low side but with in the range.
- The manufacturer control did not pick up the problem
- Rerun Previous C.A.P survey (C-B 2019)
- One C.A.P. sample was out and the rest of the P.T samples all on a negative bias .

Case study # 4 Free T3 New 6 point calibrator

Product Information on (September-10-2019)
New assay file, new reagent new calibrator (6 point)

- Unity Real Time (L.J chart) showing downwards shift

Oct-04-2019, Immunoassay plus **Lot # 40950** First Q.C post 6 point calibration.
(First 6 point calibrator)



- Problem solved with new 6 point calibrator.

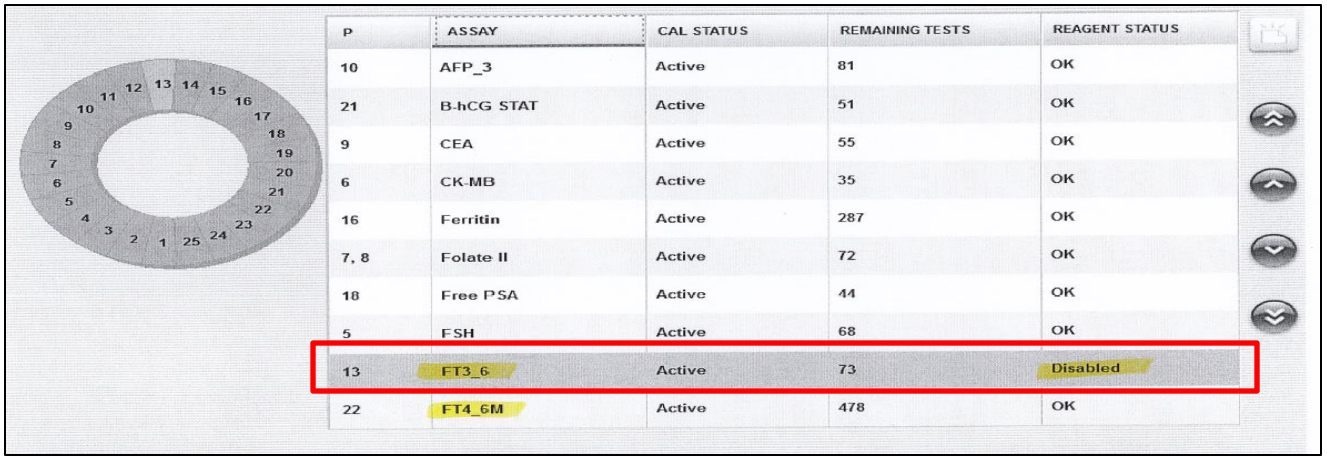
Case study # 4 Free T3 New 6 point calibrator

Product Information on (September-10-2019)

New assay file, new reagent new calibrator (6 point)

Action

- Immediately stopped the Assay (Free T3) until the correct Calibrator arrives from outside.



Why this Example ?

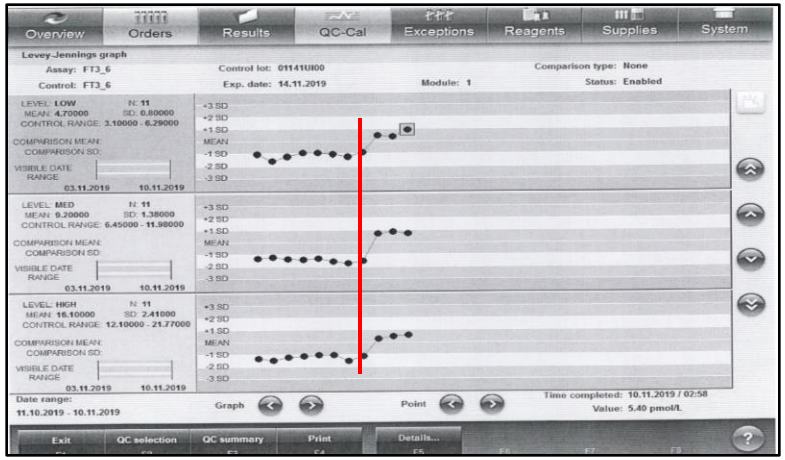
Case study # 4 Free T3 New 6 point calibrator

Product Information on (September-10-2019)

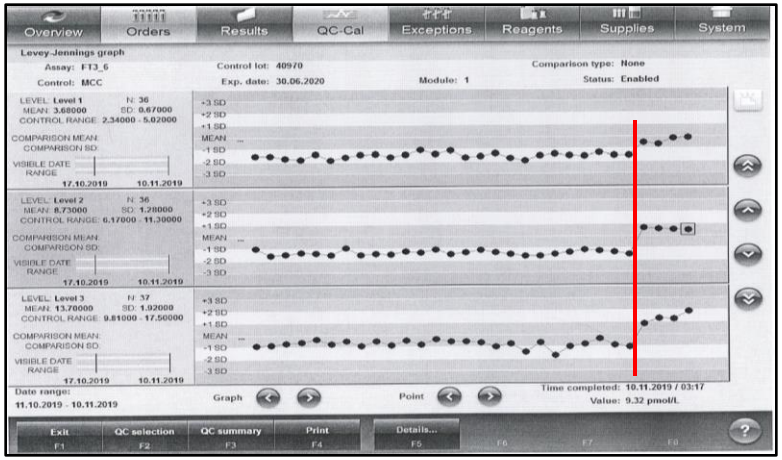
New assay file, new reagent new calibrator (6 point)

- Recalibrated using the newly arrived calibrator.

Single/Company control Lot # 01141U100



Bio-Rad Control Lot # 40970



- Problem solved, Q.C results within the acceptable range.
- Resumed testing patient samples.

Summary

4- Case # 4 (Free T3)

- New 6 point Calibrator started
- 2 lot # Bio-Rad Q.C outside range
- Independent Q.C picked up the problem
- Company Q.C. low, but in range
- C.A.P Proficiency test out
- Stopped the Assay.
- Problem solved with new Calibrator

Take Home Message

- **Medical Technologists**

  Never recalculate / re-establish Q.C range unless there is a very good justification or when it is due.

- **Companies**

  Educate clients about your products.

- **Laboratories**

  Use Independent Control

  Establish your Q.C Range

  Participate in Monthly Q.C Peer Comparison.

- **National Guard Hospital**

  Jeddah, Chemistry staff, Thank You.

Thank You

from