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EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

REFERENCE MEASUREMENT SERVICES

EDUCATION & TRAINING

Weqas | GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

Laboratory Based Case Studies and Questions

Annette Thomas & Gareth Davies

Problem Solving Checklist

Analyte	SDI Score	Precision r, IS,Sy.x,	Accuracy m,c	Previous dist.	Identify error	Possible Cause	Analyte

Case Study Example – Serum Chemistry - Calcium

Lab Code: ## · Section: ###### · Instrument: Cobas C Module

Scheme: Serum Chemistry. Distribution Code: SC0622. Distribution Date: 30/05/22. Final. Report Issued: 1/07/22						
Calcium (mmol/l)		**1**	**2**	**3**	**4**	**Analyte SDI**
Reported Result		2.61	2.13	1.68	2.79	
Method Corrected Result		2.610	2.130	1.680	2.790	
NM-BAPTA	Mean	2.459	2.025	1.583	2.675	
	SD	0.034	0.031	0.028	0.039	
	Number	72	71	72	73	
	Uncert.	0.0040	0.0037	0.0033	0.0045	
Cobas C Module	Mean	2.459	2.025	1.583	2.675	
	SD	0.034	0.031	0.028	0.039	
	Number	72	71	72	73	
	Uncert.	0.0040	0.0037	0.0033	0.0045	
Overall	Mean	2.459	2.027	1.589	2.676	
	SD	0.040	0.040	0.031	0.040	
	Number	132	132	132	131	
	Uncert.	0.0035	0.0035	0.0027	0.0035	
Reference Values FAAS / FAES		2.460	2.010	1.580	2.680	
Ref. Value Uncertainty		0.0200	0.0200	0.0200	0.0300	
Non-scoring Reference Values						
WeQas SD		0.043	0.039	0.035	0.046	
SDI		** 3.47	** 3.09	** 2.85	** 2.41	** 2.95

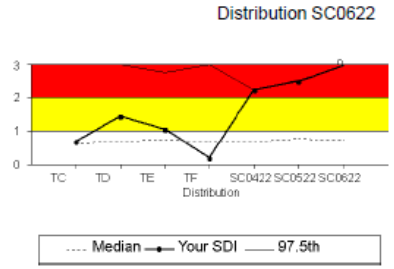
Please note: Linear regression uses CF corrected data.

Total Error

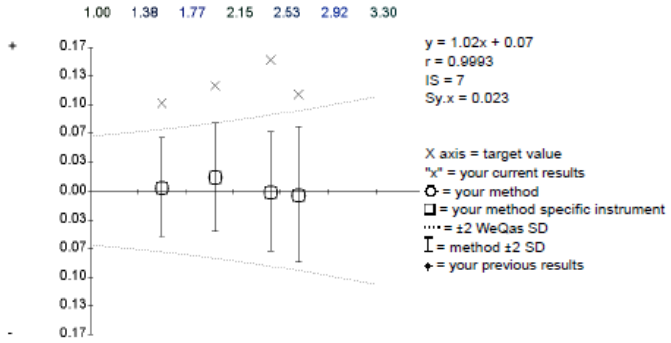
SDI is a measurement of your total error and will include both

This Distribution SC0622
Your average analyte SDI for the 4 samples is 2.95

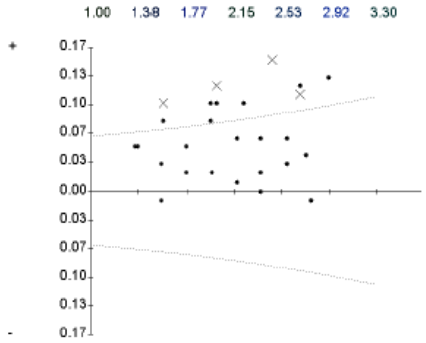
Previous SDI



This Distribution *SC0622*



Previous Distributions



Precision

This Distribution SC0622	Previous Distributions	SC0522	SC0422	TF	TE	TD	TC
Sy.x = 0.023 mmol/l	**Sy.x**	0.011	0.010	0.012	0.022	0.003	0.011
IS = 7	**IS**	3	1	2	5	0	2

Sy.x is the average deviation from the best fit line and is an index of scatter.

Precision Key

IS score	Interpretation
0 to 10	Good
11 to 150	Acceptable to Warning level
> 150	Unacceptable (including Curvilinear Data)

Accuracy

This Distribution SC0622	Previous Distributions	SC0522	SC0422	TF	TE	TD	TC
Systematic proportional error (calibration) 2.15%	**Proportional (%)**	3.86	4.70	0.07	-0.01	0.99	0.73
Systematic constant error (blank) 0.073 mmol/l	**Constant (mmol/l)**	0.017	- 0.005	- 0.004	0.040	0.036	0.012

Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

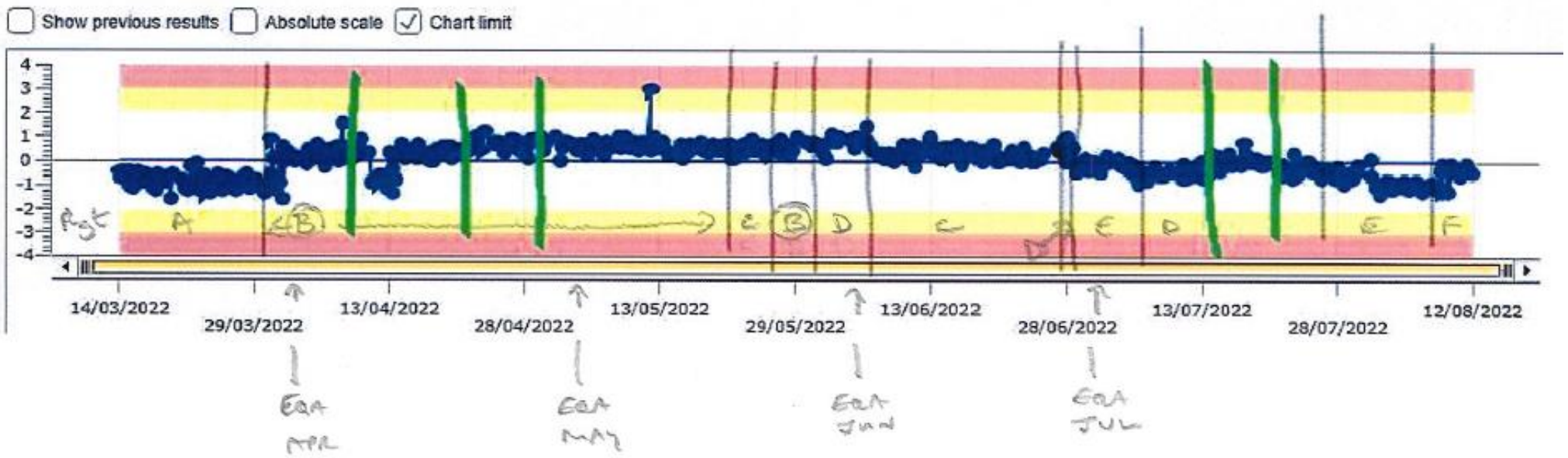
Case Study Example – Serum Chemistry - Calcium

- **Analyte:** Calcium (Serum Chemistry)
- **SDI Score:** Overall SDI score 2.95 (Poor). All samples SDI > 2
- **Precision: Sy.x** 0.023 – acceptable. **IS** 7 - good
- **Accuracy:** y = 1.02 x + 0.07. Proportional bias 2.15%, constant bias +0.073 mmol/L
- **Previous Dist / comments:** Previous SDI graph shows good SDI scores up to TF, scores significantly worse from SC0422. Problem seems to be getting worse.
- **Error Identification:** Mainly constant error but elements of both proportional and constant.
- **Possible Cause:** Calibration Issue, time expired reagents, instrument zero, instrument blank.

Case Study Example – Serum Chemistry - Calcium

- **Further Info:**
- A scheme organiser letter was sent to laboratory due to the 3 episodes of poor performance.
- Lab replied and found that the ‘higher calcium values related to a specific calibration’. This was noted on both of their analysers but more pronounced on Line 1. This was also related to a change in lot number of reagents (this was the predominant reagent in use for the relevant period)

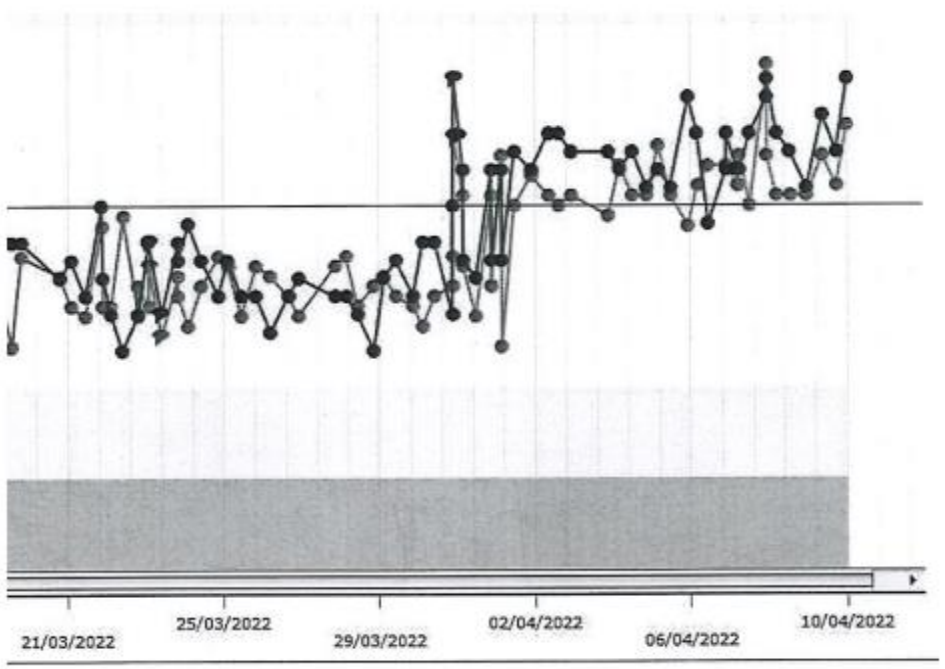
- **Annotated IQC Chart:**



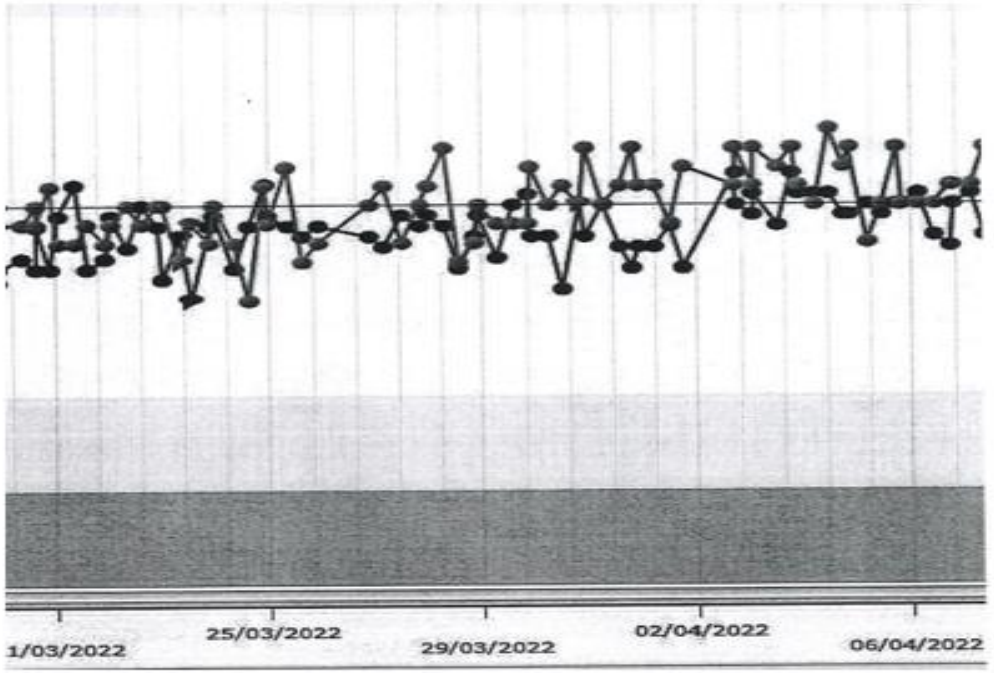
Case Study Example – Serum Chemistry - Calcium

- **IQC Charts for Line 1 and Line 2:**

Line 1

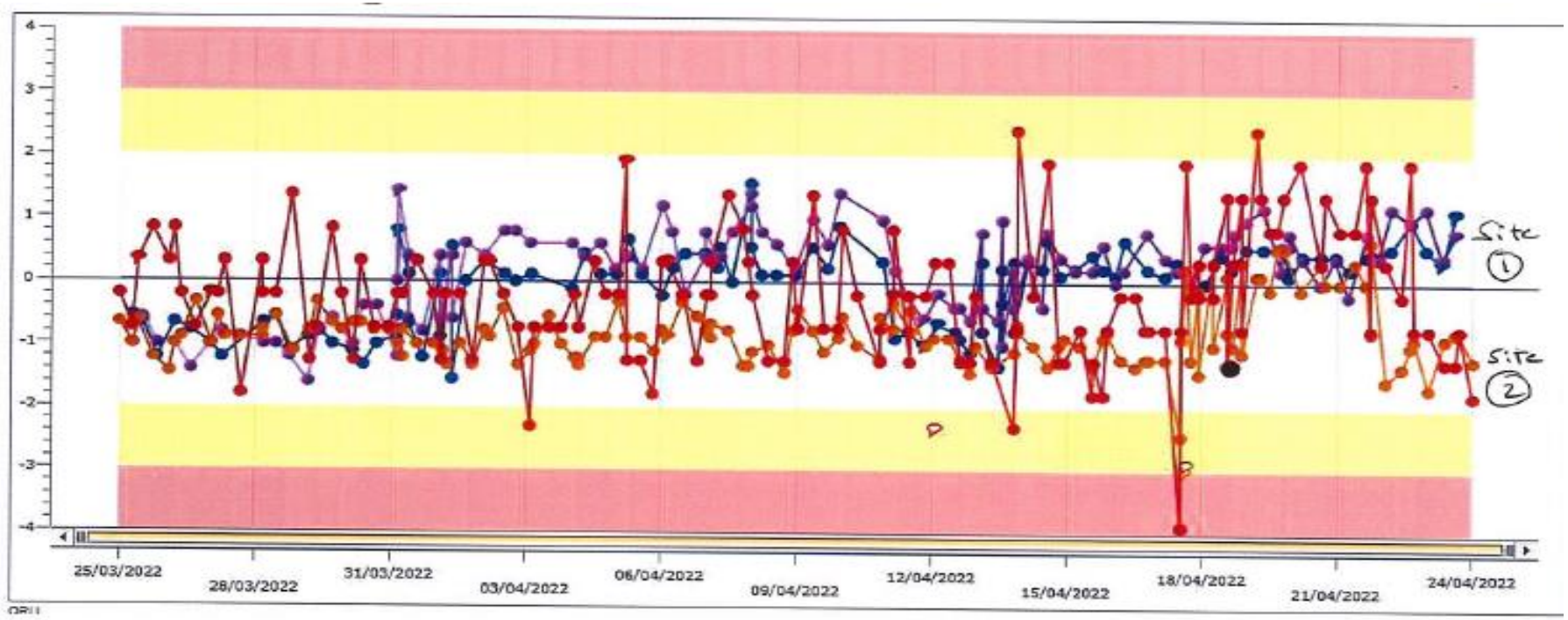


Line 2



Case Study Example – Serum Chemistry - Calcium

- **Network IQC Chart –** The analyser in question (Line 1) is the blue line – a significant shift can be seen in IQC results around late March:



Case Study Example – Serum Chemistry - Calcium

- **Outcomes from Lab:**
- Re-training and education of staff reviewing IQC who did not appreciate the significance of the shift in IQC results.
- In discussions regarding the use of ‘wider’ ‘network wide’ IQC limits to accommodate performance of analysers across the network.
- Patient results from this period were reviewed and it was felt that no detrimental affects on patient care would have arisen from this performance issue.

- **EQA Performance following re-calibration:**
- Performance improved significantly following re calibration late June and was acceptable for SC0722, and good for SC0822 and SC0922 – therefore there was no requirement to report the laboratory to the NQAAP.

Case Study 1 – Serum Chemistry - Bicarbonate

Lab Code: ## · Section: ###### · Instrument: **Architect**

Scheme: Serum Chemistry. Distribution Code: SN. Distribution Date: 7/09/20. Final. Report Issued: 30/09/20						
Bicarbonate (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		16	18	22	16	
Method Corrected Result		16.0	18.0	22.0	16.0	
PEP Carboxylase	Mean	19.0	21.3	27.8	21.9	
	SD	1.1	1.1	1.4	1.3	
	Number	87	86	85	85	
	Uncert.	0.11	0.12	0.15	0.14	
Architect	Mean	16.0	18.3	22.7	17.0	
	SD	0.8	0.5	0.5	2.2	
	Number	3	3	3	3	
	Uncert.	0.47	0.27	0.27	1.25	
Overall	Mean	19.3	21.6	28.0	22.1	
	SD	1.3	1.3	1.4	1.4	
	Number	99	99	95	96	
	Uncert.	0.13	0.13	0.15	0.14	
Reference Values						
Ref. Value Uncertainty						
Non-scoring Reference Values						
WeQas SD		1.2	1.2	1.5	1.3	
SDI		** -2.57	** -2.62	** -3.89	** -4.63	** 3.43

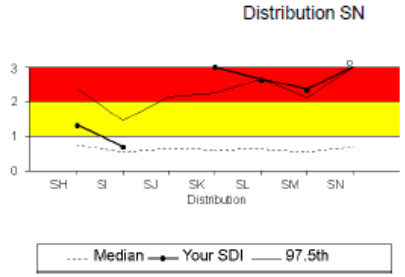
Please note: Linear regression uses CF corrected data.

Total Error

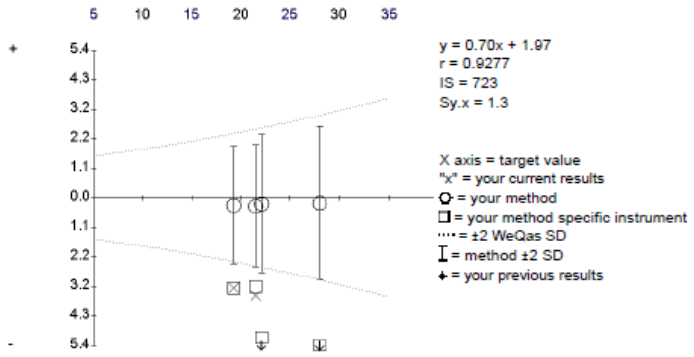
SDI is a measurement of your total error and will include both ir

This Distribution SN
Your average analyte SDI for the 4 samples is 3.43

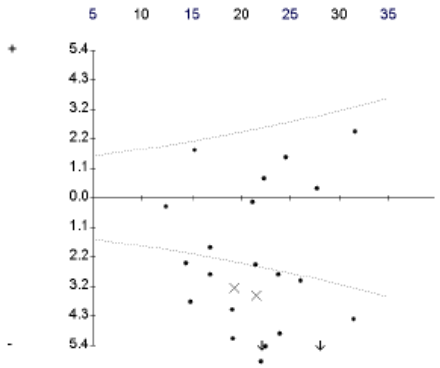
Previous SDI



This Distribution *SN*



Previous Distributions



Precision

This Distribution SN	Previous Distributions	SM	SL	SK	SJ	SI	SH
Sy.x = 1.3 mmol/l	**Sy.x**	1.7	1.5	0.8		1.2	0.8
IS = 723	**IS**	790	198	190	0	74	39

Sy.x is the average deviation from the best fit line and is an index of scatter.

Precision Key

IS score	Interpretation
0 to 10	Good
11 to 150	Acceptable to Warning level
> 150	Unacceptable (including Curvilinear Data)

Accuracy

This Distribution SN	Previous Distributions	SM	SL	SK	SJ	SI	SH
Systematic proportional error (calibration) -29.55%	**Proportional (%)**	-14.29	-6.57	-18.46		10.52	4.55
Systematic constant error (blank) 2.0 mmol/l	**Constant (mmol/l)**	- 0.1	- 2.2	- 1.0	0.0	- 2.6	0.5

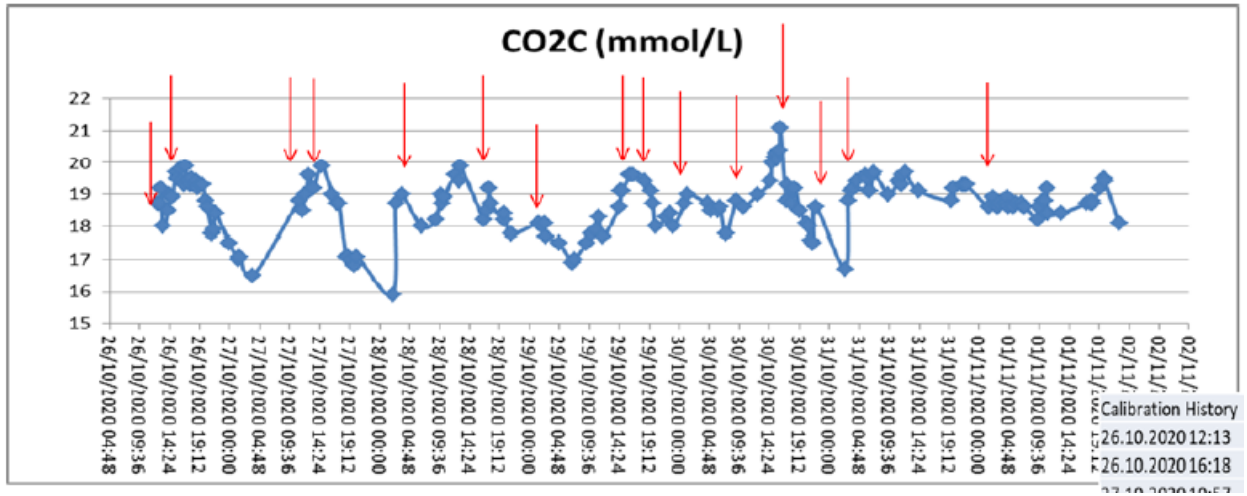
Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

Case Study 1 – Serum Chemistry - Bicarbonate

- **Analyte:** Bicarbonate (Serum Chemistry)
- **SDI Score:** Overall SDI score 3.43 (Poor). All samples SDI > 2
- **Precision: Sy.x** 1.3 – unacceptable. **IS** 723 - unacceptable
- **Accuracy:** y = 0.70 x + 1.97. Proportional bias -29.55%, constant bias +2.0 mmol/L
- **Previous Dist / comments:** Previous SDI graph shows good SDI scores for SH and SI. Non-return for SJ. Poor scores from SK.
- **Error Identification:** Error of precision and accuracy - both proportional and constant error.
- **Possible Cause:** Calibration Issue, time expired reagents, instrument zero, instrument blank.

Case Study 1 – Serum Chemistry - Bicarbonate

- **Further Info:**
- A scheme organiser letter was sent to laboratory due to the 4 episodes of poor performance.
- Lab has noted assay issues for over 6 months. Patient samples are analysed in batches rather than in random access mode.
- Lab found that EQA samples had been analysed on Instrument in question when patient samples were being assayed on another instrument so this assay was not being well controlled at time of EQA
- Also see assay drift after calibration:



Case Study 1 – Serum Chemistry - Bicarbonate

- **Analyte:** Bicarbonate (Serum Chemistry)
- **SDI Score:** Overall SDI score 3.43 (Poor). All samples SDI > 2
- **Precision: Sy.x** 1.3 – unacceptable. **IS** 723 - unacceptable
- **Accuracy:** y = 0.70 x + 1.97. Proportional bias -29.55%, constant bias +2.0 mmol/L
- **Previous Dist / comments:** Previous SDI graph shows good SDI scores for dist SH and SI. Non-return for SJ. Poor scores from SK.
- **Error Identification:** Error of precision and accuracy - both proportional and constant error.
- **Possible Cause:** Calibration Issue, time expired reagents, instrument zero, instrument blank.
- **Outcome:**
- Improve sample handling of EQA samples
- Introduction of aqueous standard for bicarb as supplementary IQC
- Look at ways of improving drift in assay ? More frequent calibration ? Sample throughout and time on analyser

Case Study 2 – Lipids – LDL Cholesterol

Lab Code: ## · Section: ###### · Instrument: **AU2700/AU5400/AU5800**

Scheme: Lipid. Distribution Code: LP0521. Distribution Date: 24/05/21. Final. Report Issued: 21/06/21						
LDL Cholesterol (mmol/l)		**1**	**2**	**3**	**4**	**Analyte SDI**
Reported Result			2.15	3.37	1.36	
Method Corrected Result			2.150	3.370	1.360	
Friedewald formula	Mean	1.766	1.787	2.897	1.100	
	SD	0.186	0.122	0.163	0.088	
	Number	17	111	103	109	
	Uncert.	0.0564	0.0145	0.0201	0.0106	
AU2700/AU5400/AU5800	Mean	1.814	1.908	2.965	1.172	
	SD	0.131	0.100	0.191	0.069	
	Number	5	11	11	11	
	Uncert.	0.0733	0.0377	0.0718	0.0259	
Overall	Mean	1.837	1.782	2.855	1.100	
	SD	0.183	0.118	0.206	0.086	
	Number	29	124	115	122	
	Uncert.	0.0425	0.0133	0.0241	0.0097	
Reference Values						
Ref. Value Uncertainty						
Non-scoring Reference Values						
WeQas SD		0.149	0.147	0.178	0.130	
SDI			** 2.46	** 2.67	2.00	** 2.38

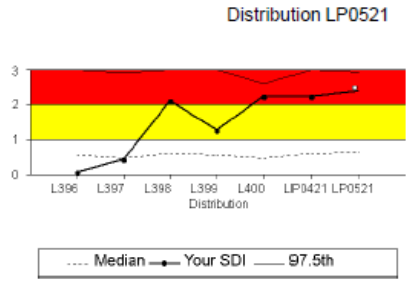
Please note: Linear regression uses CF corrected data.

Total Error

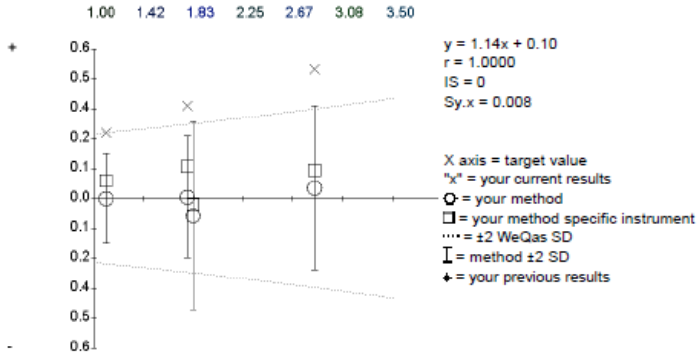
SDI is a measurement of your total error and will include both

This Distribution LP0521
Your average analyte SDI for the 4 samples is 2.38

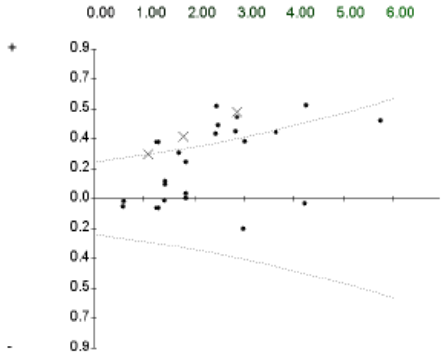
Previous SDI



This Distribution *LP0521*



Previous Distributions



Precision

This Distribution LP0521	Previous Distributions	LP0421	L400	L399	L398	L397	L396
Sy.x = 0.008 mmol/l	**Sy.x**	0.032	0.050	0.060	0.179	0.097	0.020
IS = 0	**IS**	1	7	25	57	13	2

Sy.x is the average deviation from the best fit line and is an index of scatter.

Precision Key

IS score	Interpretation
0 to 10	Good
11 to 150	Acceptable to Warning level
> 150	Unacceptable (including Curvilinear Data)

Accuracy

This Distribution LP0521	Previous Distributions	LP0421	L400	L399	L398	L397	L396
Systematic proportional error (calibration) 14.46%	**Proportional (%)**	0.17	4.38	34.58	14.03	-0.99	3.48
Systematic constant error (blank) 0.104 mmol/l	**Constant (mmol/l)**	0.452	0.246	- 0.434	- 0.008	- 0.039	- 0.044

Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

Case Study 2 – Lipids – LDL Cholesterol

- **Analyte:** LDL Cholesterol (Lipids)
- **SDI Score:** Overall SDI score 2.38 (Poor). All samples SDI ≥ 2. Sample 1 no return for LDL – correct due to high Trig in sample.
- **Precision: Sy.x** 0.008 – good. **IS** 0 - good
- **Accuracy:** y = 1.14 x + 0.1. Proportional bias +14.46%, constant bias +0.104 mmol/L
- **Previous Dist / comments:** Previous SDI graph shows worsening performance, poor from dist L400.
- **Error Identification:** Error of accuracy – mainly proportional error.
- **Possible Cause:** Calculated parameter - ? Correct Formula used ? Issue with measured analytes used in formula

Case Study 2 – Lipids – Cholesterol Report

Scheme: Lipid. Distribution Code: LP0521. Distribution Date: 24/05/21. Final. Report Issued: 21/06/21						
Cholesterol (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		5.60	3.90	5.90	2.80	
Method Corrected Result		5.600	3.900	5.900	2.800	
Cholesterol oxidase	Mean	5.121	3.674	5.359	2.634	
	SD	0.113	0.093	0.121	0.068	
	Number	119	120	120	120	
	Uncert.	0.0129	0.0106	0.0138	0.0078	
AU2700/AU5400/AU5800	Mean	5.224	3.729	5.537	2.668	
	SD	0.147	0.105	0.155	0.072	
	Number	10	10	10	10	
	Uncert.	0.0582	0.0417	0.0615	0.0284	
Overall	Mean	5.123	3.677	5.353	2.635	
	SD	0.116	0.092	0.128	0.068	
	Number	126	127	127	127	
	Uncert.	0.0129	0.0102	0.0142	0.0076	
Reference Values CDC		5.184	3.695	5.392	2.666	
Ref. Value Uncertainty		0.0140	0.0140	0.0490	0.0070	
Non-scoring Reference Values ID-GCMS		5.290	3.690	5.530	2.700	
WeQas SD		0.218	0.156	0.228	0.112	
SDI		**1.91**	**1.31**	**** 2.23**	**1.20**	**1.66**

Sigma Metrics			
Critical Level 1: 5.0 mmol/l			
Minimum Acceptable score	1.67	Critical Level 1 Sigma score	0.2
MAPS Allowable TE	8.5%		
MAPS Allowable bias %	4.0%	Lab |bias| %	8.3%
MAPS Allowable CV %	2.7%	Lab CV %	0.9%

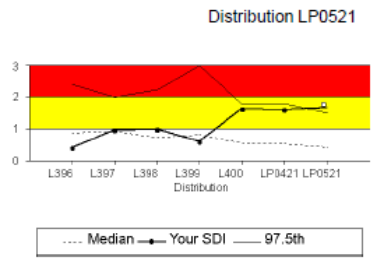
Please note: Linear regression uses CF corrected data.

Total Error

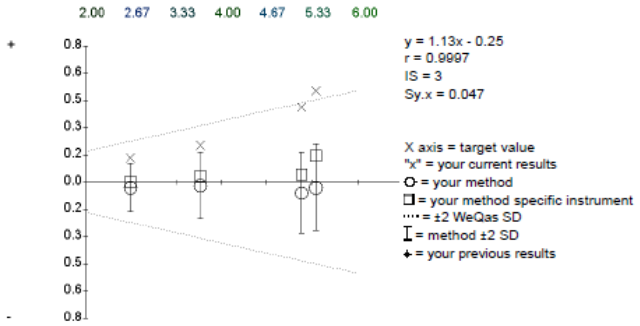
SDI is a measurement of your total error and will include both i

This Distribution LP0521
Your average analyte SDI for the 4 samples is 1.66

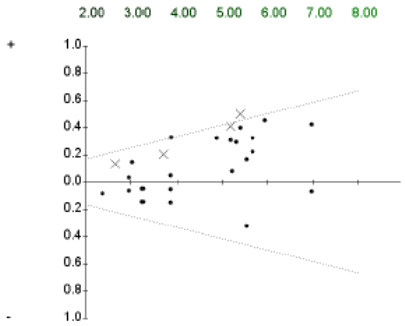
Previous SDI



This Distribution *LP0521*



Previous Distributions



Case Study 2 – Lipids – LDL Cholesterol

- **Analyte:** LDL Cholesterol (Lipids)
- **SDI Score:** Overall SDI score 2.38 (Poor). All samples SDI ≥ 2. Sample 1 no return for LDL – correct due to high Trig in sample.
- **Precision: Sy.x** 0.008 – good. **IS** 0 - good
- **Accuracy:** y = 1.14 x + 0.1. Proportional bias +14.46%, constant bias +0.104 mmol/L
- **Previous Dist / comments:** Previous SDI graph shows worsening performance, poor from dist L400.
- **Error Identification:** Error of accuracy – mainly proportional error.
- **Possible Cause:** Calculated parameter - ? Correct Formula used ? Issue with measured analytes used in formula
- **Cholesterol Performance**: SDI on dist LP0521 1.66 – positive bias
- **Actual Cause:** Incorrect calibrator values on Cholesterol used – IDGCMS calibrator values not CDC values.

Case Study 3 – Serum Chemistry – CKD-EPI eGFR

Lab Code: ## · Section: ###### · Instrument: **AU2700/AU5400/AU5800**

Scheme: Serum Chemistry. Distribution Code: SN.
Distribution Date: 7/09/20. Final. Report Issued: 30/09/20

CKD-EPI eGFR (ml/min)		1	2	3	4	Analyte SDI
Reported Result		33	24	10	85	
Method Corrected Result		33.0	24.0	10.0	85.0	
CKD-EPI	Mean	26.4	19.4	8.0	57.3	
	SD	1.0	0.9	0.1	2.7	
	Number	74	75	65	71	
	Uncert.	0.12	0.10	0.01	0.32	
AU2700/AU5400/AU5800	Mean	28.0	20.3	8.0	61.8	
	SD	2.7	1.9	0.6	7.5	
	Number	9	9	8	8	
	Uncert.	0.89	0.63	0.23	2.65	
Overall	Mean	26.4	19.4	8.0	57.3	
	SD	1.0	0.9	0.1	2.7	
	Number	74	75	65	71	
	Uncert.	0.12	0.10	0.01	0.32	
Reference Values CKD-EPI		26.6	19.7	8.0		
Ref. Value Uncertainty						
Non-scoring Reference Values						
WeQas SD		1.2	0.9	0.6	3.1	
SDI		** 5.61	** 5.09	** 3.54	** 8.98	** 5.81

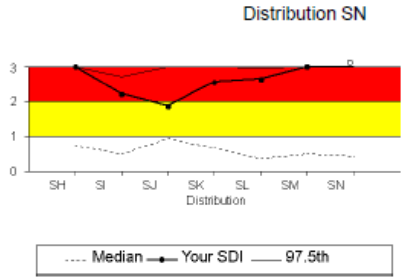
Please note: Linear regression uses CF corrected data.

Total Error

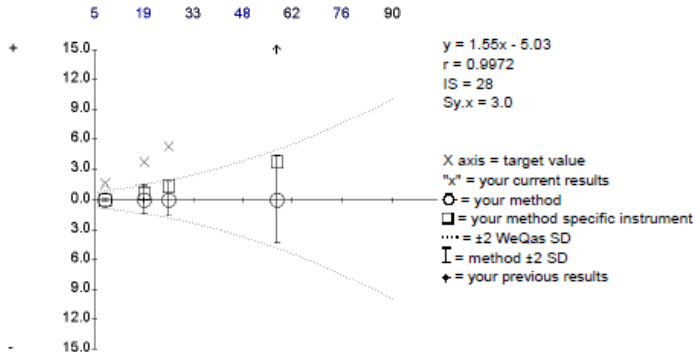
SDI is a measurement of your total error and will include both

This Distribution SN
Your average analyte SDI for the 4 samples is 5.81

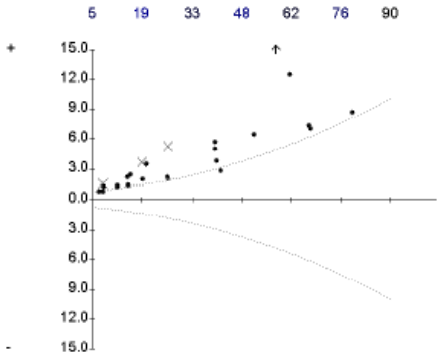
Previous SDI



This Distribution *SN*



Previous Distributions



Precision

This Distribution SN	Previous Distributions	SM	SL	SK	SJ	SI	SH
Sy.x = 3.0 ml/min	**Sy.x**	1.0	0.4	0.8	0.0	0.1	0.2
IS = 28	**IS**	3	1	3	0	0	0

Sy.x is the average deviation from the best fit line and is an index of scatter.

Precision Key

IS score	Interpretation
0 to 10	Good
11 to 150	Acceptable to Warning level
> 150	Unacceptable (including Curvilinear Data)

Accuracy

This Distribution SN	Previous Distributions	SM	SL	SK	SJ	SI	SH
Systematic proportional error (calibration) 54.86%	**Proportional (%)**	13.66	16.51	15.85	6.65	12.62	24.99
Systematic constant error (blank) - 5.0 ml/min	**Constant (ml/min)**	0.6	- 0.4	- 0.8	0.6	- 0.0	- 1.0

Bias includes components of proportional and constant errors. A proportional bias suggests an error of calibration whilst a constant bias suggests a blank error. Mixed errors will include significant components of both.

Case Study 3 – Serum Chemistry – CKD-EPI eGFR

- **Analyte:** CKD-EPI eGFR (Serum Chemistry)
- **SDI Score:** Overall SDI score 5.81 (Poor). All samples SDI > 2
- **Precision: Sy.x** 3 – acceptable. **IS** 28 - acceptable
- **Accuracy:** y = 1.55 x – 5.03. Proportional bias +54.86%, constant bias -5.0
- **Previous Dist / comments:** Previous SDI graph shows consistent poor scores
- **Error Identification:** Error of accuracy – predominantly proportional error.
- **Possible Cause:** Calculated parameter - ? Correct Formula used ? Issue with measured analytes used in formula

Case Study 3 – Serum Chemistry – Creatinine Report

Lab Code: ## · Section: ###### · Instrument: **AU2700/AU5400/AU5800**

Scheme: Serum Chemistry. Distribution Code: SN. Distribution Date: 7/09/20. Final. Report Issued: 30/09/20						
Creatinine (µmol/L)		**1**	**2**	**3**	**4**	**Analyte SDI**
Reported Result		235	307	513	58	
Method Corrected Result		235.0	307.0	513.0	58.0	
Jaffe - IDMS	Mean	276.3	354.7	593.4	83.6	
	SD	11.6	15.0	26.0	5.6	
	Number	74	76	76	74	
	Uncert.	1.35	1.72	2.98	0.65	
AU2700/AU5400/AU5800	Mean	258.5	337.3	569.0	74.2	
	SD	11.9	9.2	16.8	2.5	
	Number	12	11	11	11	
	Uncert.	3.43	2.77	5.07	0.76	
Overall	Mean	279.3	359.2	601.1	83.8	
	SD	11.2	13.4	22.4	4.2	
	Number	184	181	181	177	
	Uncert.	0.83	0.99	1.66	0.31	
Reference Values ID-GCMS		281.2	361.7	602.8		
Ref. Value Uncertainty		1.74	2.24	3.74		
Non-scoring Reference Values						
WeQas SD		11.1	15.2	34.2	5.5	
SDI		** -3.72	** -3.14	** -2.35	** -4.69	** 3.48
Sigma Metrics						
Critical Level 1: 75 µmol/L						
Minimum Acceptable score	1.67	Critical Level 1 Sigma score				0.0
MAPS Allowable TE	9.5%					
MAPS Allowable bias %	5.0%	Lab |bias| %				22.3%
MAPS Allowable CV %	2.7%	Lab CV %				2.5%

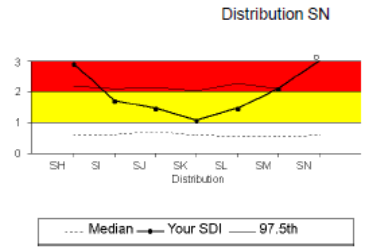
Please note: Linear regression uses CF corrected data.

Total Error

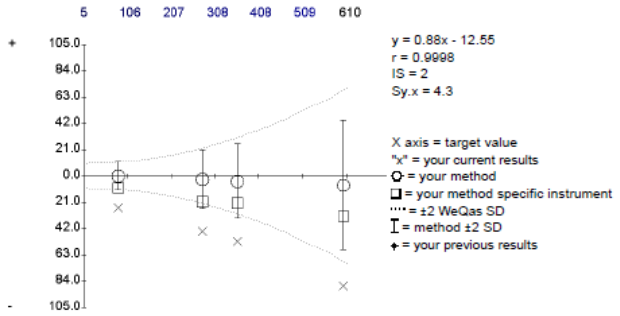
SDI is a measurement of your total error and will include both in

This Distribution SN
Your average analyte SDI for the 4 samples is 3.48

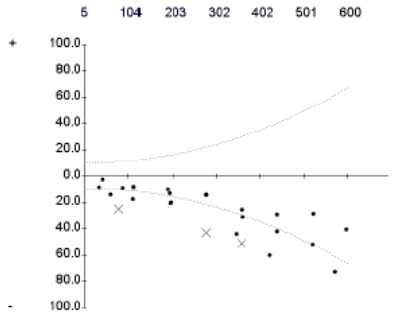
Previous SDI



This Distribution *SN*



Previous Distributions



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- **Error Identification:** Error of accuracy – predominantly proportional error.
- **Possible Cause:** Calculated parameter - ? Correct Formula used ? Issue with measured analytes used in formula
- **Creatinine Performance**: SDI on dist BZ 3.48
- **Actual Cause:** Use of paediatric settings on 1 site compared to other site using 'normal' settings resulted in approx. 5% lower Creatinine values. Instrument group mean Negative to reference value – this lab even more Negative than method mean resulting in poor SDI
- **Outcome:** Settings not changed – Manufacturer in to assist - Gradual improvement seen. Performance now generally acceptable / good