Weqas Report Interpretation

Samantha Jones / Gareth Davies

Weqas

Summary of Talk

- Weqas report format
  - *Target value
  - *Performance Criteria
- Basic statistics
  - *Imprecision
  - *Inaccuracy

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Weqas Report Format

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Quantitative Programmes

- Serum Chemistry
- Lipids
- Bilirubin
- ED Toxicology
- Urine Chemistry / Oxalate & Citrate
- Blood Gases / Co-oximetry
- Endocrine
- Haematinics
- Cardiac Marker
- BNP / NT Pro BNP
- HbA1c
- Homocysteine
- Bile Acids
- Serum ACE
- Serum hCG
- Porphyrin
- Ammonia
- CRP / POCT CRP
- TDM / IS
- POCT Creatinine
- Procalcitonin
- D-dimer

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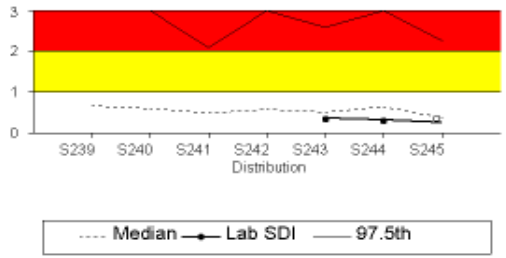
General Overview report of lab (section)
SDI scores

Distribution Date: 24/10/17. Final. Report Issued: 28/11/17

This Distribution	
Overall Lab SDI:	0.24
Median All Laboratory:	0.38
97.5th centile:	2.27



All SDI Ranges	
< 1	Good
1 - 2	Acceptable
> 2	Poor

Section SDI scores for this distribution

Section	Cobas e601
Overall	**0.24**
Cortisol	0.24
Progesterone	0.36
Oestradiol	0.06
Testosterone	0.49
Total T4	?
Total T3	?
Free T4	0.07
Free T3	0.15
TSH	0.32
LH	0.19
FSH	0.33
Prolactin	0.16

click for further details on individual analyte performance

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Analyte detailed report

Scheme: Endocrine. Distribution Code: S245.
Distribution Date: 24/10/17. Final. Report Issued: 28/11/17

Cortisol (nmol/L)		1	2	3	4	5	6	Analyte SDI
Reported Result		288.1	170.2	353.7	370.2	1064.0	72.0	
Method Corrected Result		288.10	170.20	353.70	370.20	1064.00	72.00	
Elecsys/E Module	Mean	306.62	184.24	381.54	396.64	1129.40	72.25	
	SD	15.54	15.43	27.02	30.21	60.83	1.09	
	Number	5	5	5	5	5	4	
	Uncert.	6.950	6.903	12.083	13.512	27.204	0.545	
Cobas E Module	Mean	306.62	184.24	381.54	396.64	1129.40	72.25	
	SD	15.54	15.43	27.02	30.21	60.83	1.09	
	Number	5	5	5	5	5	4	
	Uncert.	6.950	6.903	12.083	13.512	27.204	0.545	
Overall	Mean	282.70	163.62	347.38	359.41	1083.57	69.54	
	SD	22.83	12.82	22.16	33.15	50.95	3.90	
	Number	19	18	18	19	18	10	
	Uncert.	5.237	3.022	5.224	7.606	12.009	1.233	
Reference Values ID-LC-MS/MS		298.36	177.20	356.88	377.36	1065.45		
Ref. Value Uncertainty		6.100	3.600	7.300	7.700	21.800		
Non-scoring Reference Values								
WeQas SD		30.30	18.19	36.87	38.10	111.75	8.62	
SDI		**0.18**	**0.36**	**0.17**	**0.28**	**-0.18**	**0.29**	**0.24**

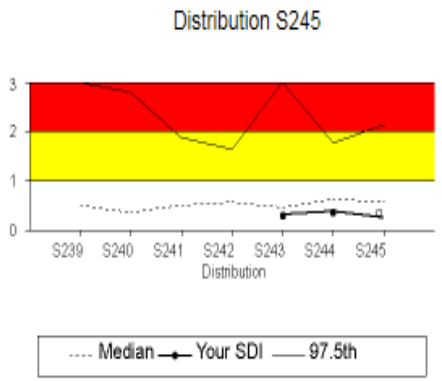
Please note: Linear regression uses CF corrected data.

Total Error

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

This Distribution S245
Your average analyte SDI for the 6 samples is 0.24

Previous SDI



Ref Values used for SDI and Sigma Scoring

Performance Criteria

SDI Score

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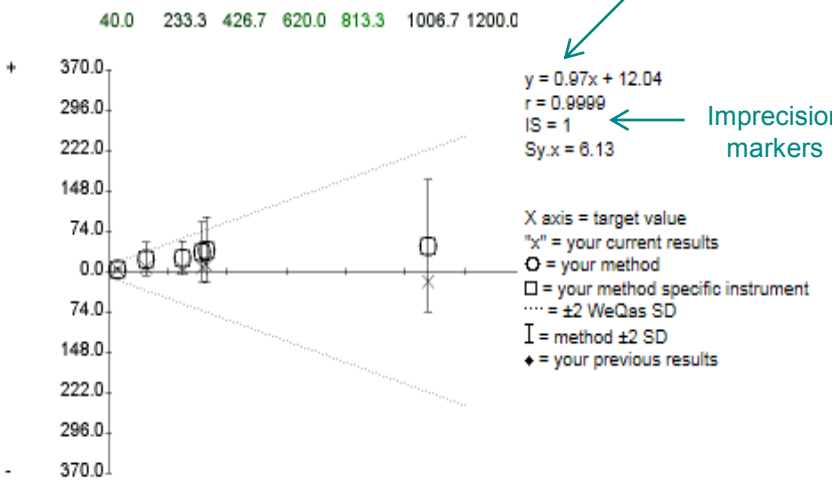
Analyte detailed report

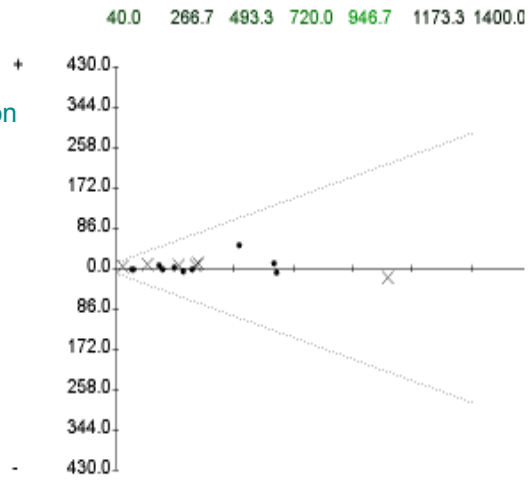
This Distribution *S245*

Linear Regression Equation



Imprecision markers

Previous Distributions



Precision

This Distribution S245	Previous Distributions	S244	S243	S242	S241	S240	S239
Sy.x = 6.13 nmol/L IS = 1	**Sy.x**	4.46	27.15				
	IS	2	53	0	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 S245	Previous Distributions	S244	S243	S242	S241	S240	S239
Systematic proportional error (calibration) -2.61% Systematic constant error (blank) 12.04 nmol/L	**Proportional (%)**	2.11	3.08				
	Constant (nmol/L)	- 14.46	- 5.24	0.00	0.00	0.00	0.00

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.

Current slope and intercept
y = 0.97x + 12.04

Previous slope and intercept values

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How do we set Performance Specifications and Target Values?

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The Weqas Report
Target values used in Statistical Analysis

Hierarchy

Reference values – used for bias plot /SDI calculation and σ score

Method mean – used for SDI calc if no ref and n>8

Overall mean – used for SDI calc and bias plot if no ref and n <8

Analyser mean – on report for information only

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Generation of Reference Target Values

- Specialist Laboratories Required
- Accredited to ISO17025 and ISO15195
- Limited number of laboratories worldwide

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Value of Reference Targets

- Traceable to higher order
- Establishes method traceability for the lab – requirement of ISO 15189
- Highlights the pitfalls of using the trimmed overall mean as an accuracy target in EQA Schemes
- Useful in the post market vigilance of the IVD - Directive
- Required for UK MAPS

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Determining analytical quality specifications

Allowable Total Analytical Error (TEa) encompasses both imprecision and inaccuracy.

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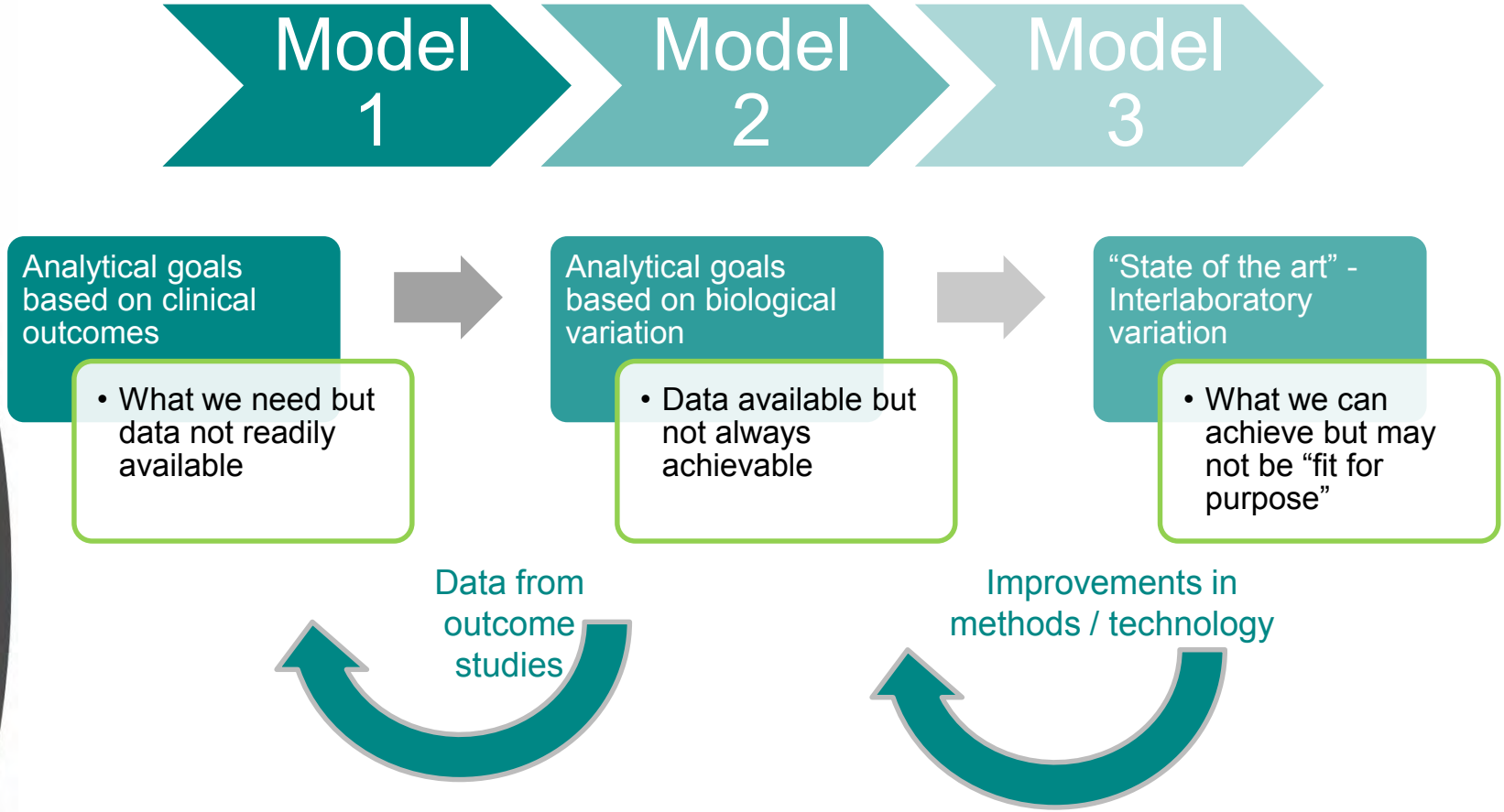
Analytical goal Hierarchy



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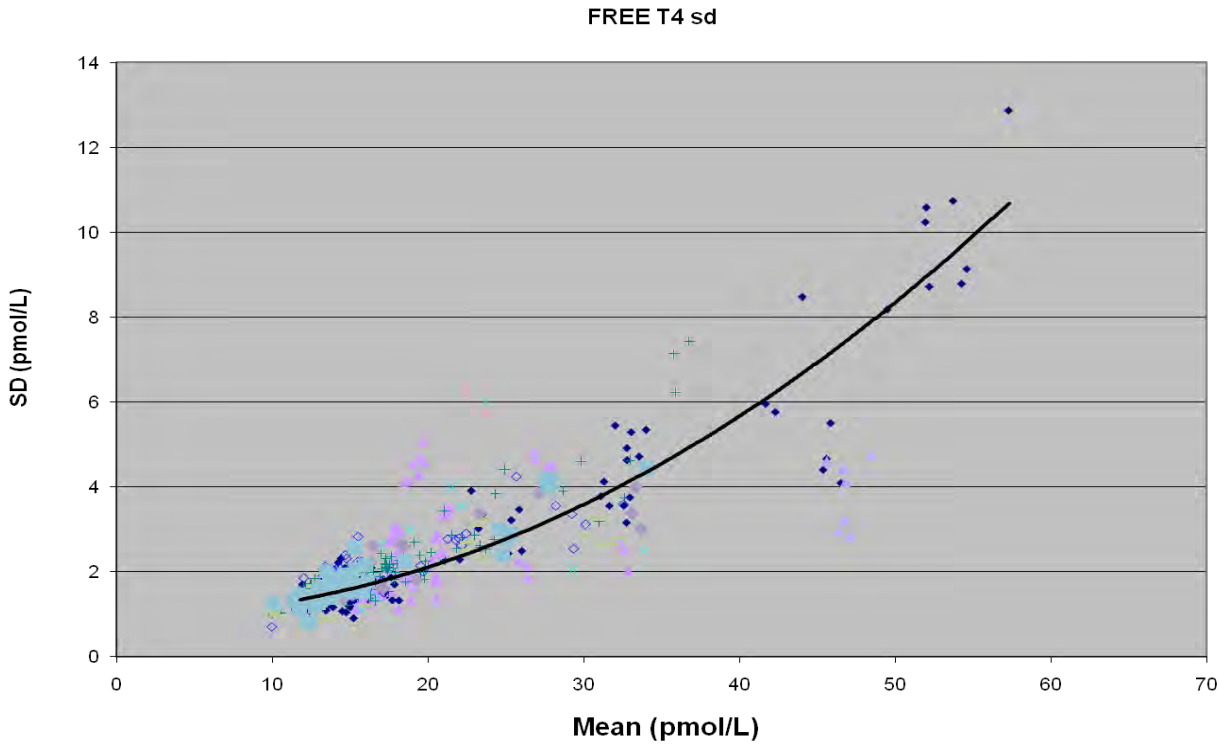
Interlaboratory variation

FT4



Relationship of analyte conc. to SD follows a polynomial equation for most analytes and is non linear therefore using fixed % TE is not appropriate

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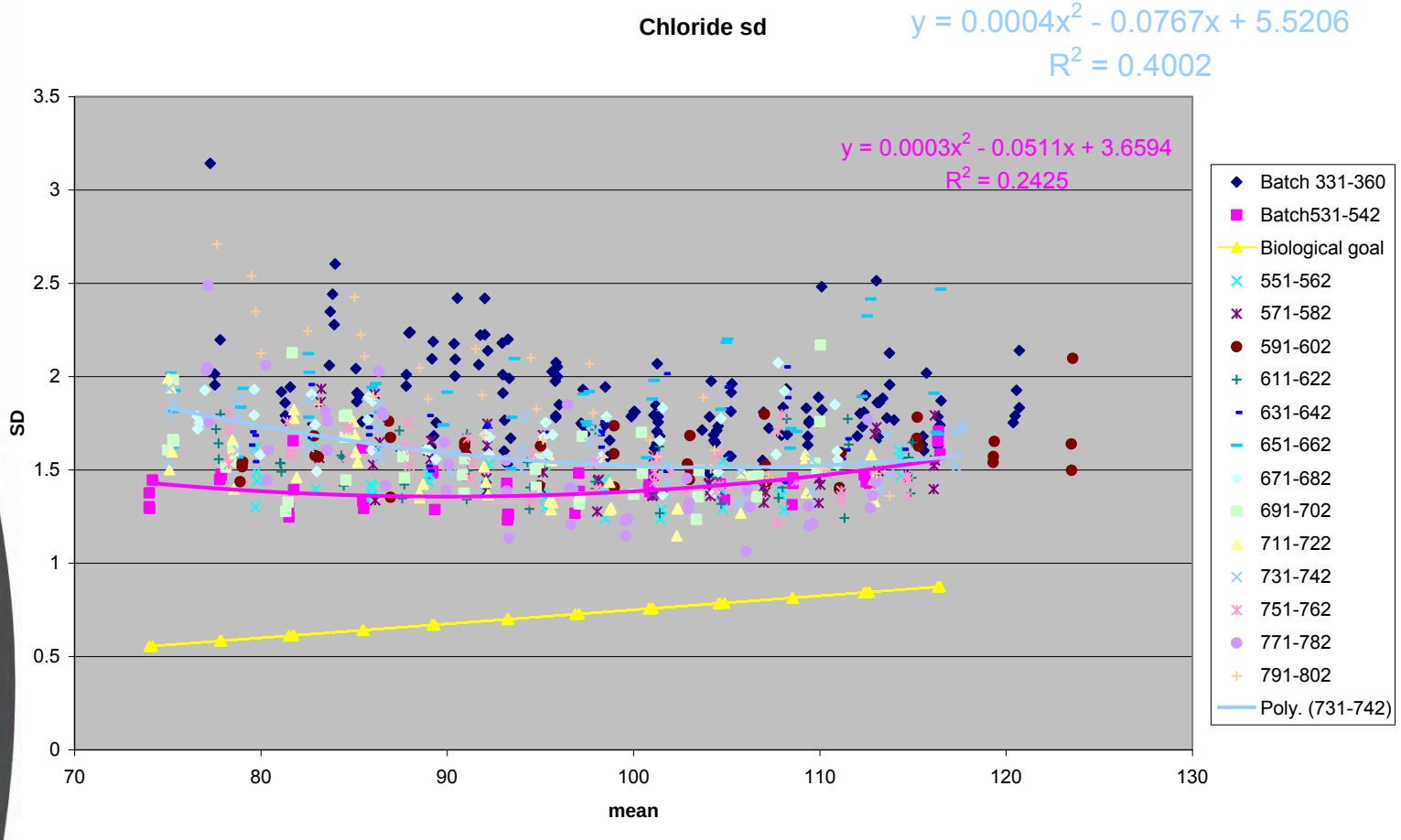
“State of the art” v Biology



Biological goals not achievable. Performance has not improved over time.

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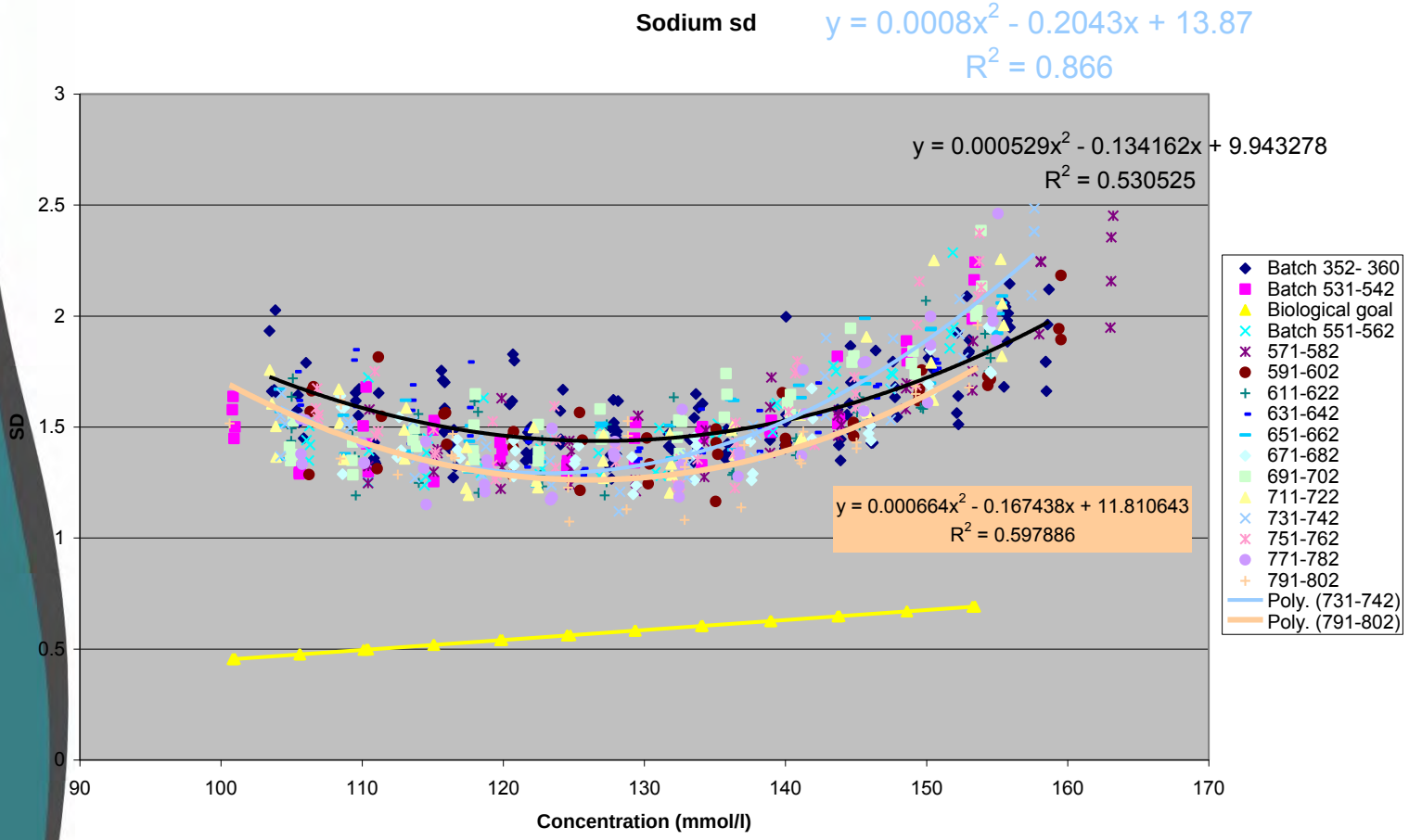

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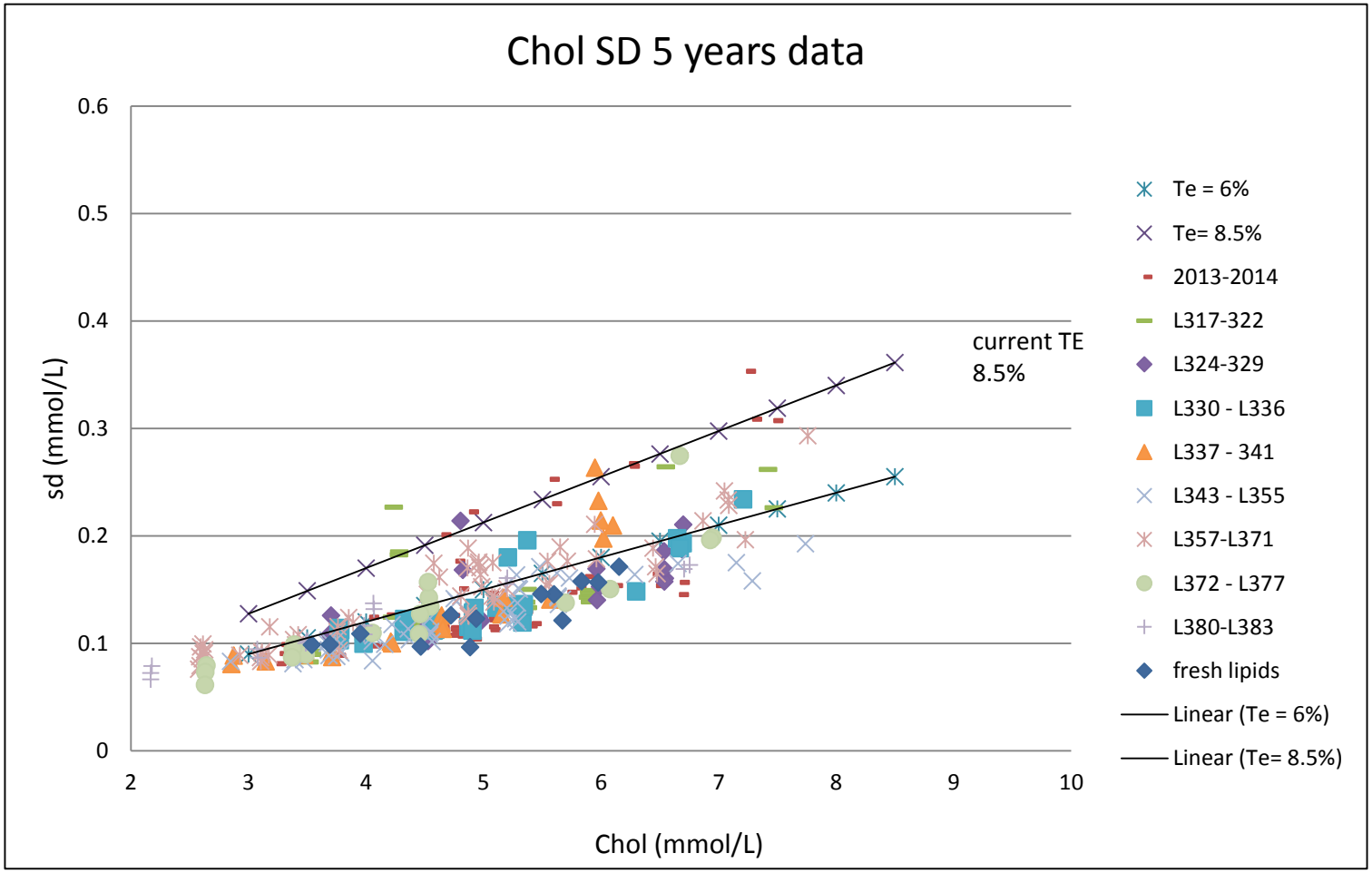

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Performance criteria = Target value +/- TE

Allowable TE = 2*Weqas SD

Quality Indicators

SDI = (lab result-target value)/WEQAS SD

To be within performance criteria SDI < 2

Sigma score based on UK MAPS criteria

Sigma metric: $[(TE_a - bias_{obs})/s_{obs}]$

Total Allowable Error as defined by MAPS

Laboratory bias at critical level

Within run CV (%)

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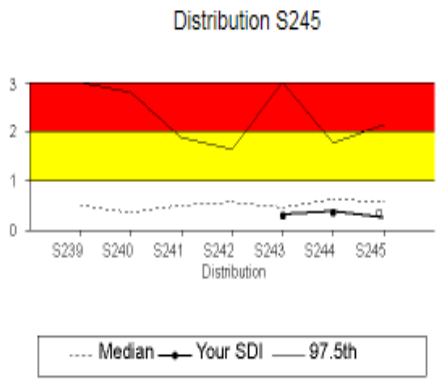

Ref Values used for SDI and Sigma Scoring

Performance Criteria Target

SDI Score

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The WEQAS Report Statistical Indices

- Imprecision: Sy.x, r, IS
- Inaccuracy: Bias plot, y=mx+c

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Interpretation of Imprecision Markers

Sy.x is the deviation around the best fit line and is an indication of scatter. It is used as an index of within run precision. This is given in the units of the analyte in question.

Correlation coefficient (**r value**) is also an index of within run precision. The closer to 1.0 the value is, the better the precision (less scatter about the best fit line).

IS score is derived from the correlation coefficient.

$$IS = (1-r)*10{,}000$$

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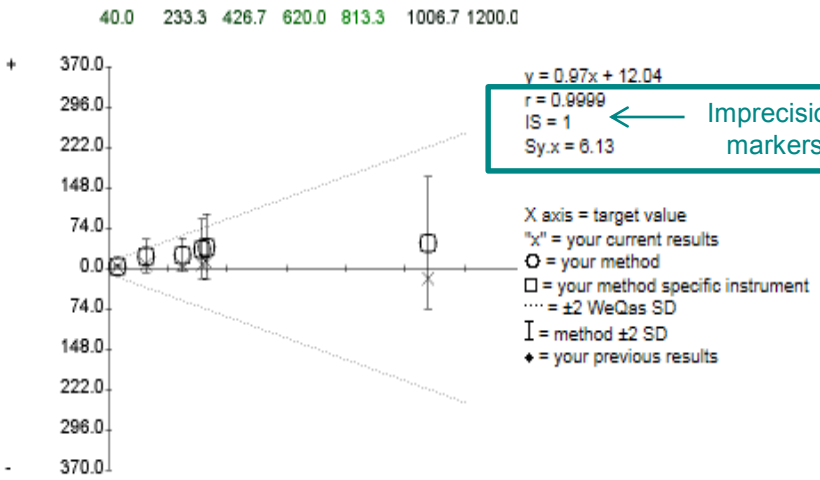
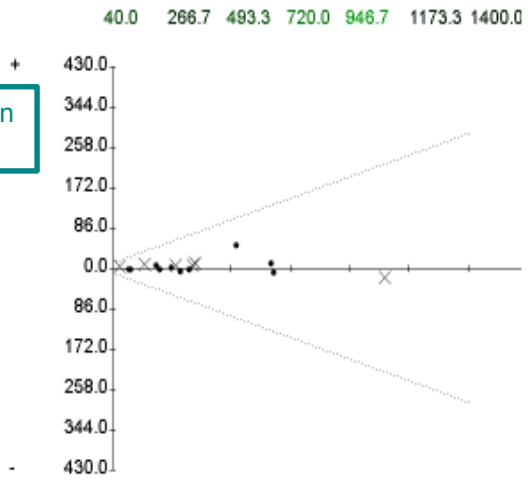
Analyte detailed report

This Distribution *S245*



Previous Distributions



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The Sy.x explained

Standard deviation

$$SD = \sqrt{\frac{\Sigma\,(\bar{y}-y)^2}{d.f.}}$$

where

$\bar{y}$ = observed value

y = expected value

d.f. = degrees of freedom

Standard dev of residuals

$$Sy.x = \sqrt{\frac{\Sigma\,(\tilde{y}-y)^2}{d.f.}}$$

where

$\tilde{y}$ = the value on the line of best fit

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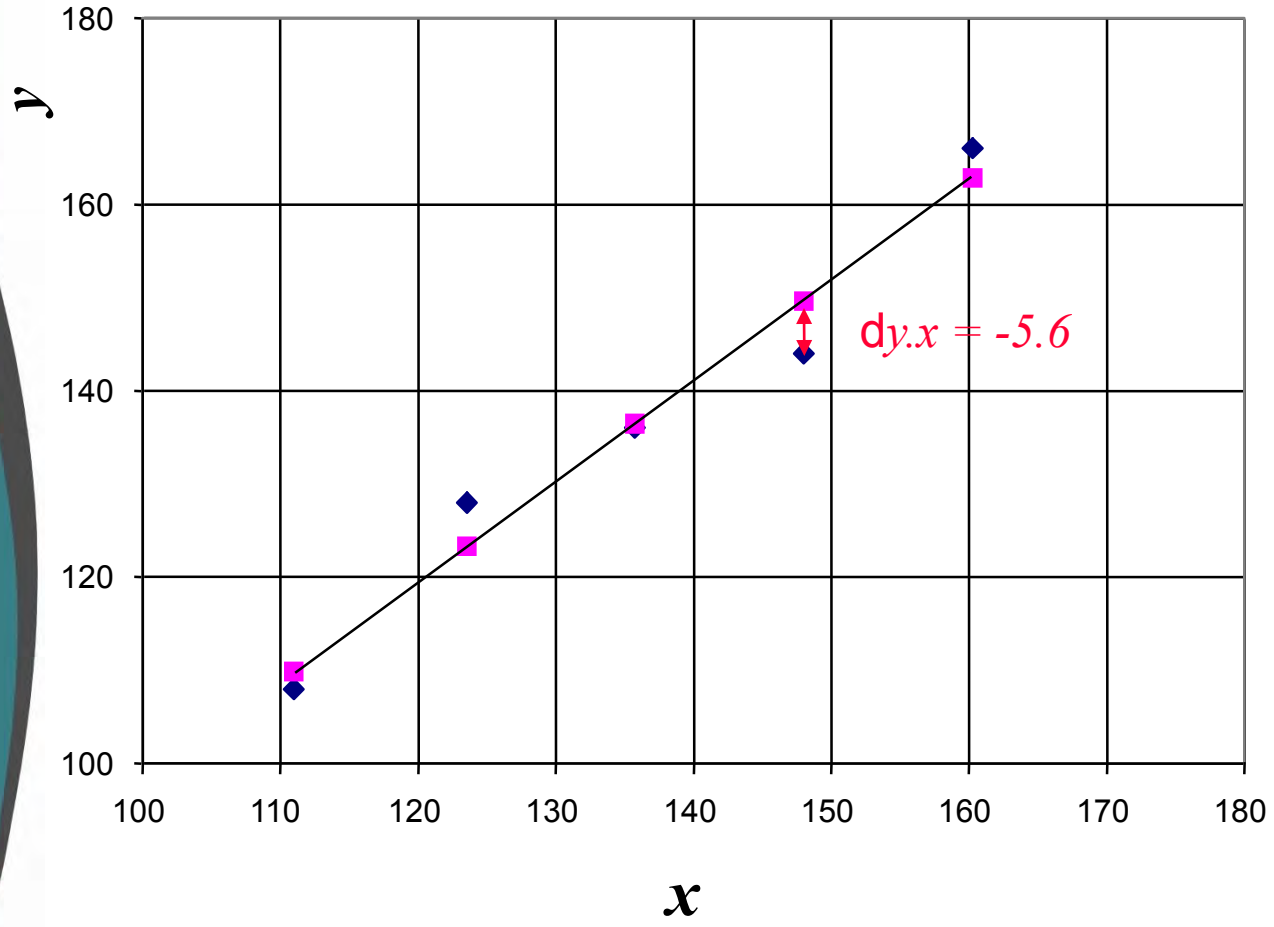
Imprecision

Sodium (mmol/l)



r = 1.000
IS = 0
Sy.x = 0

r = 0.9812
IS = 188
Sy.x= 4.7

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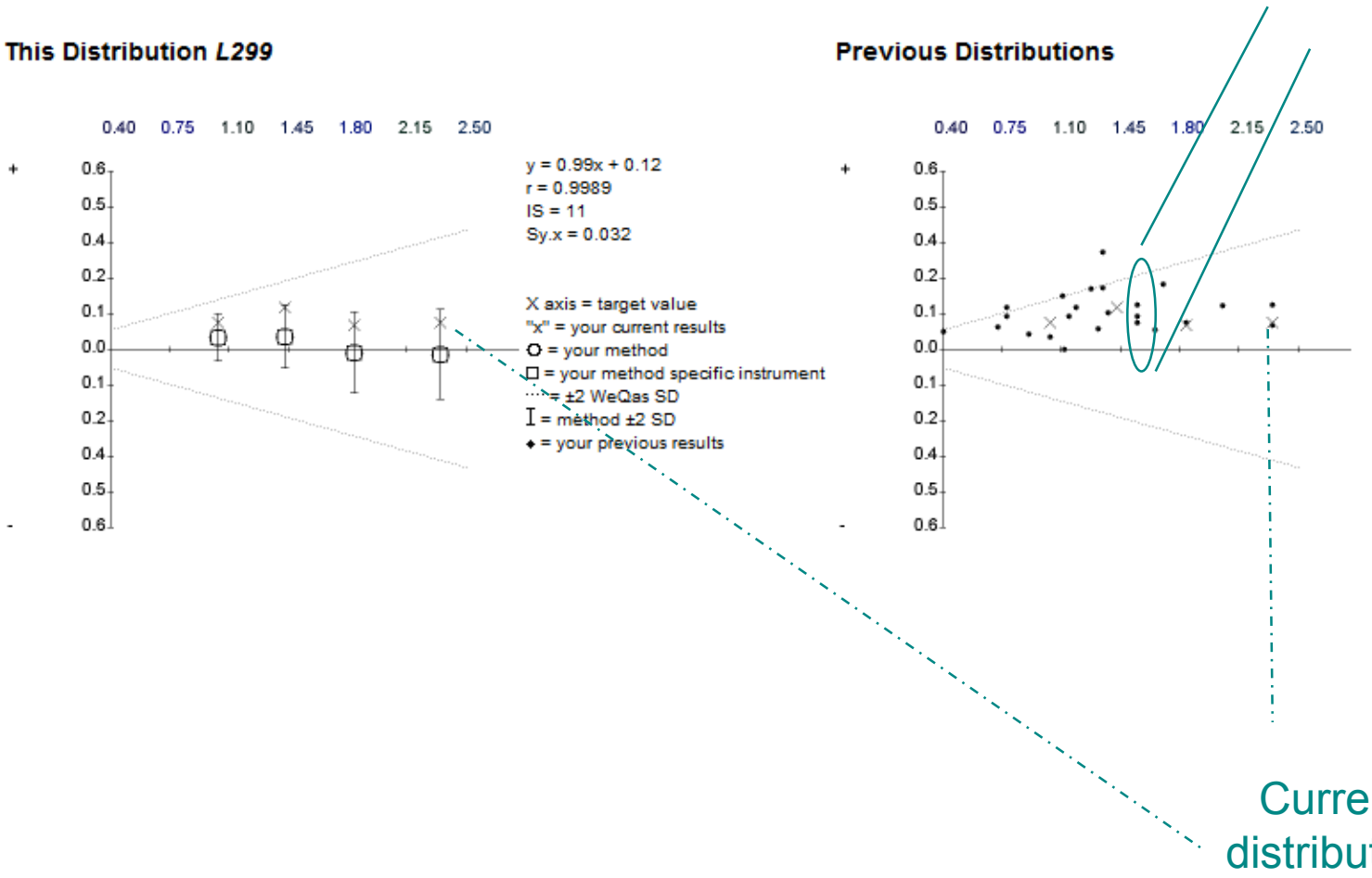
Between batch precision



Current distribution

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Interpretation of Accuracy Markers

Represents the point at which the line crosses the y axis. This is shown in the units of measurement of each analyte. In the example this is 12.04nmol/L. If deemed significant, this indicates a constant error.

$$y = mx + c$$

Represents the slope – in the example this is 0.97 which shows a 3% negative proportional bias. If deemed significant indicates a proportional error.

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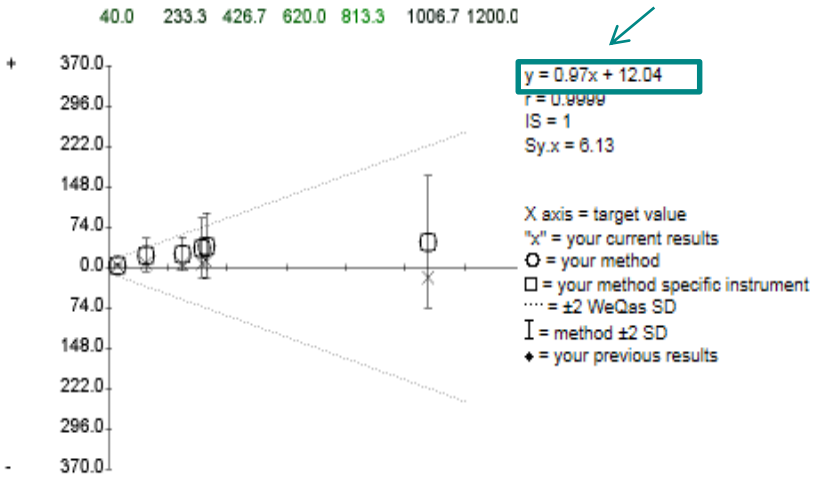
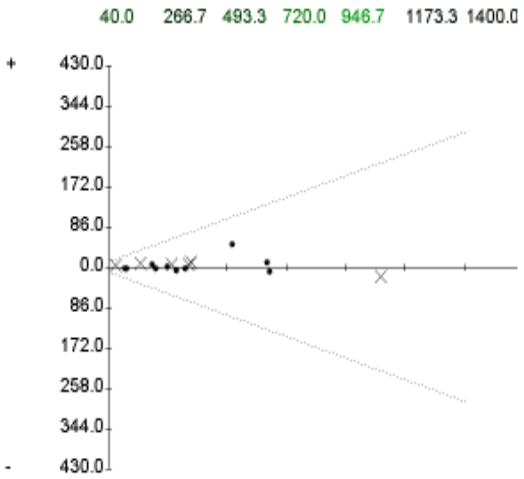
Accuracy Markers

This Distribution *S245*

Linear Regression Equation



Previous Distributions



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Current slope and intercept
y = 0.97x + 12.04

Previous slope and intercept values

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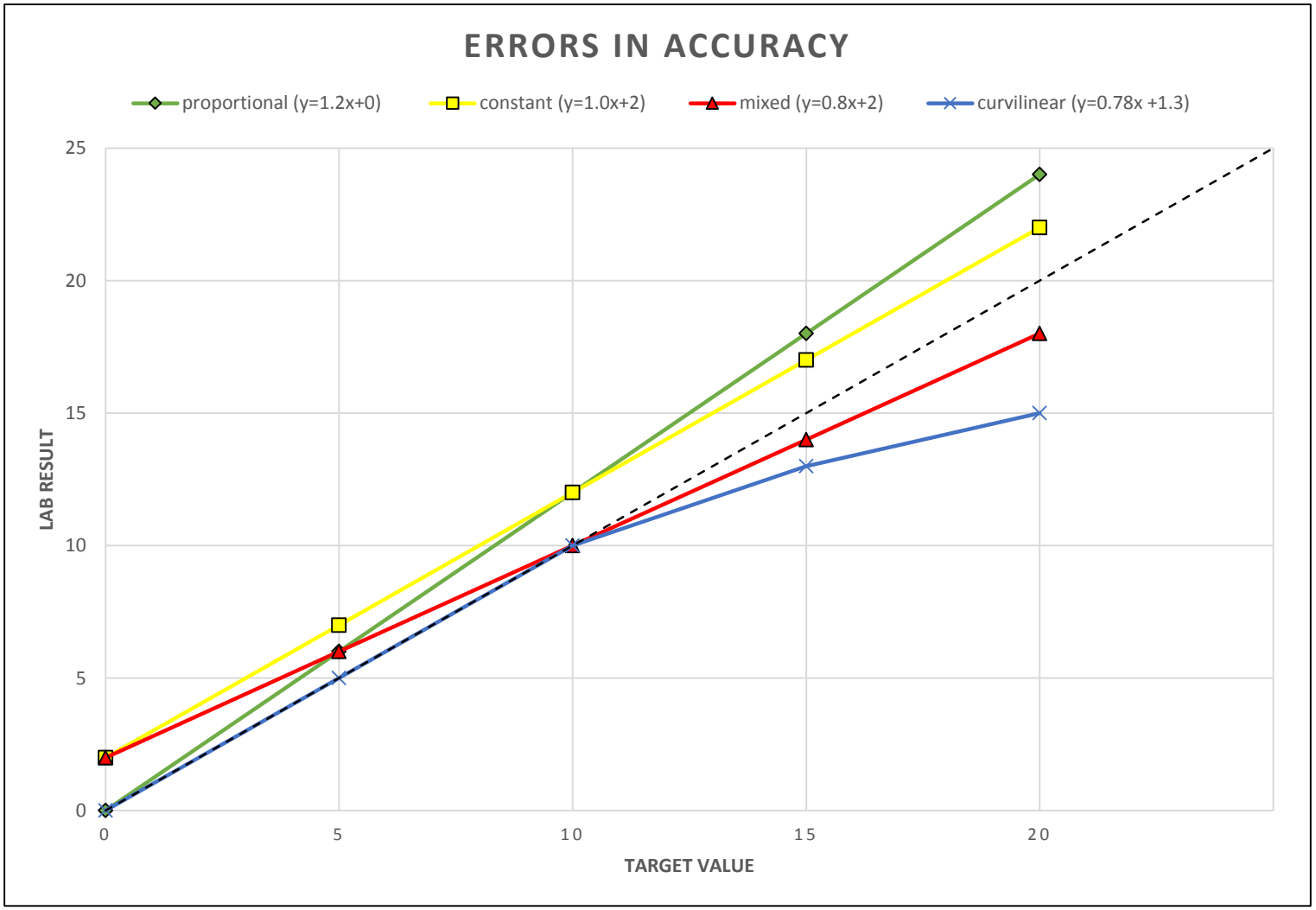
ERRORS IN ACCURACY
proportional (y=1.2x+0)
constant (y=1.0x+2)
mixed (y=0.8x+2)
curvilinear (y=0.78x +1.3)
LAB RESULT
TARGET VALUE
0
5
10
15
20
25

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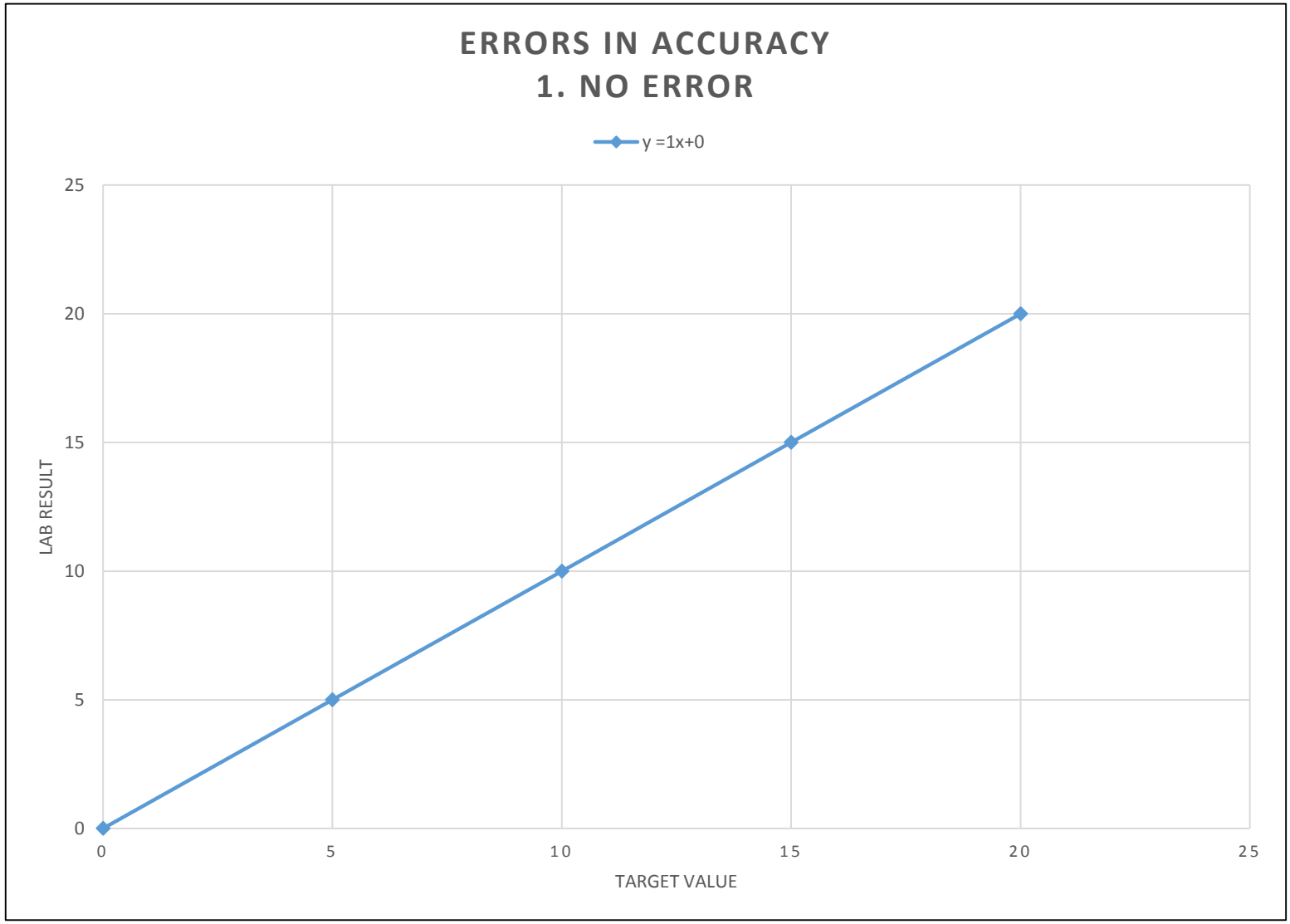
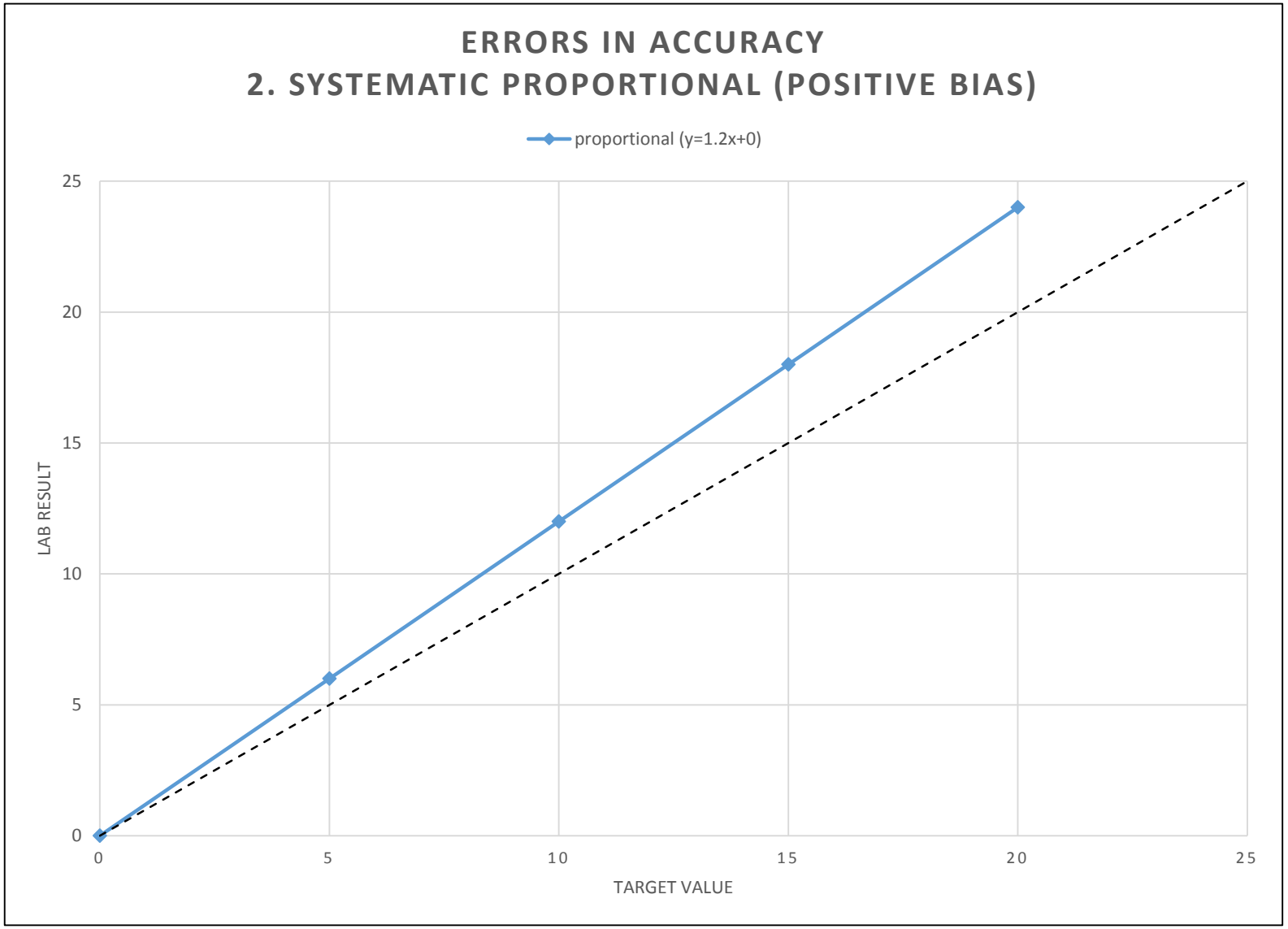

ERRORS IN ACCURACY
1. NO ERROR
y =1x+0
25
20
15
10
5
0
LAB RESULT
0
5
10
15
20
25
TARGET VALUE

Weqas


ERRORS IN ACCURACY
2. SYSTEMATIC PROPORTIONAL (POSITIVE BIAS)
proportional (y=1.2x+0)
LAB RESULT
TARGET VALUE
0
5
10
15
20
25

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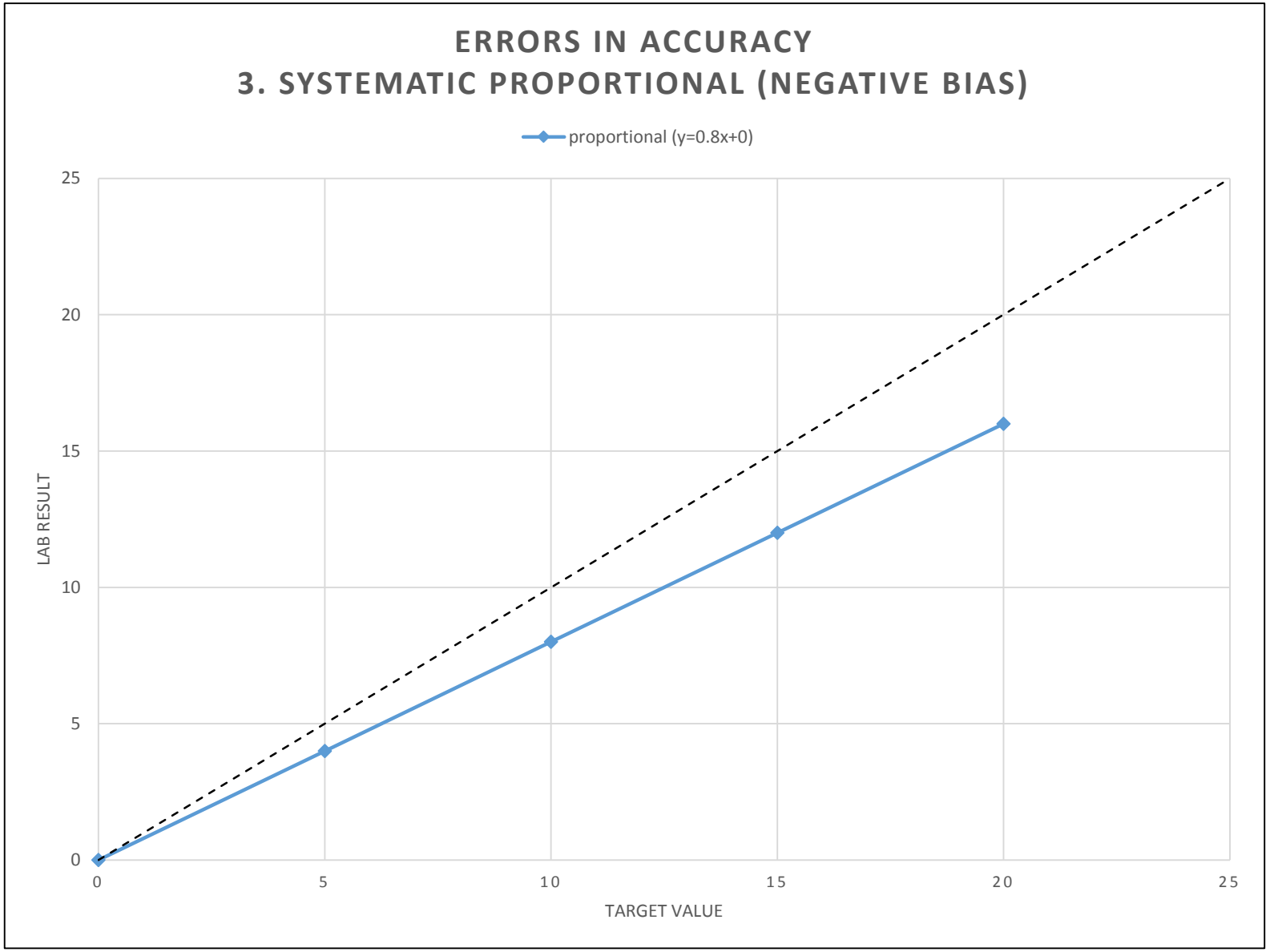
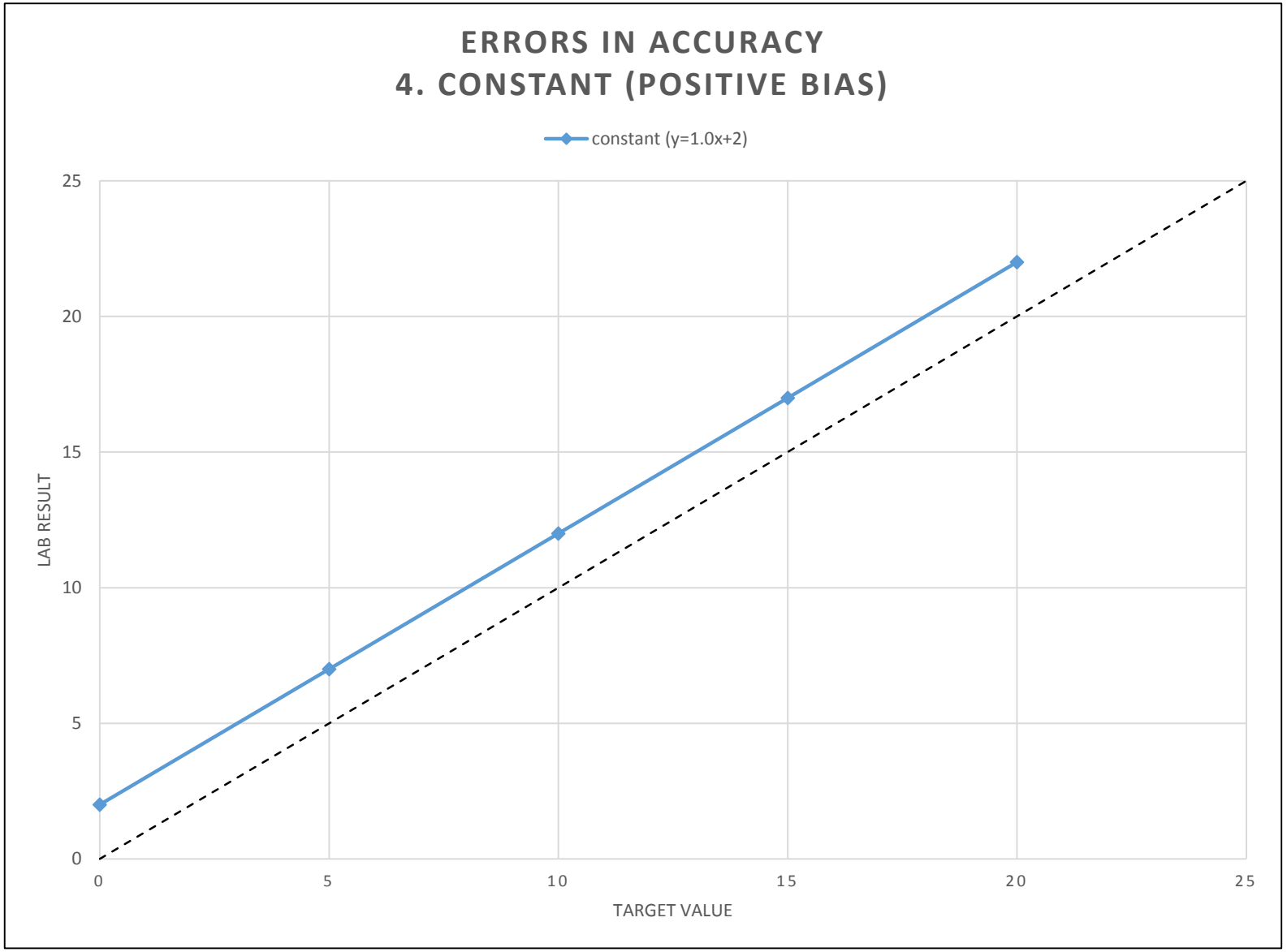
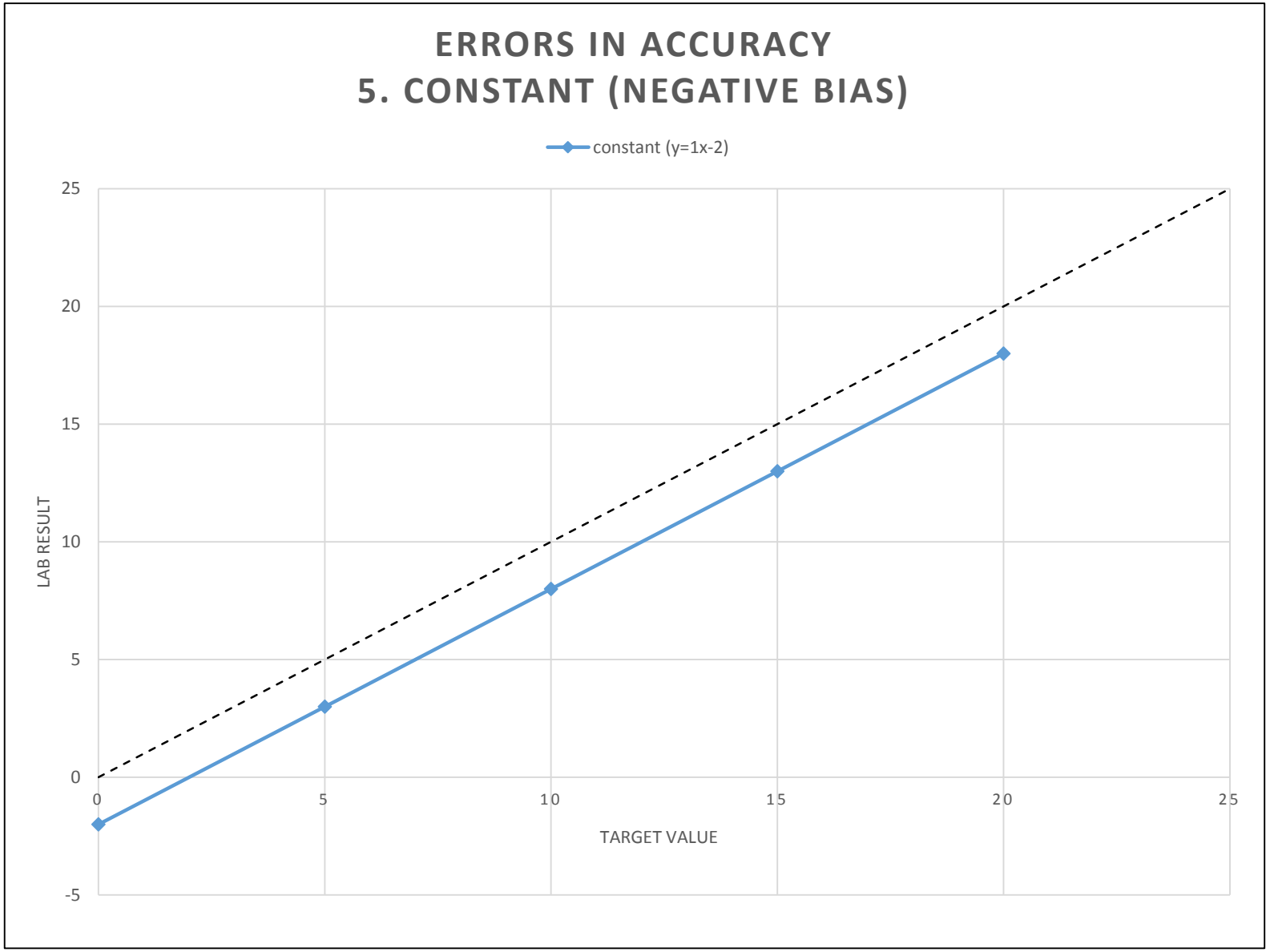

ERRORS IN ACCURACY
3. SYSTEMATIC PROPORTIONAL (NEGATIVE BIAS)
proportional (y=0.8x+0)
LAB RESULT
TARGET VALUE
0
5
10
15
20
25

Weqas


ERRORS IN ACCURACY
4. CONSTANT (POSITIVE BIAS)
constant (y=1.0x+2)
LAB RESULT
TARGET VALUE
0
5
10
15
20
25

Weqas

ERRORS IN ACCURACY
5. CONSTANT (NEGATIVE BIAS)



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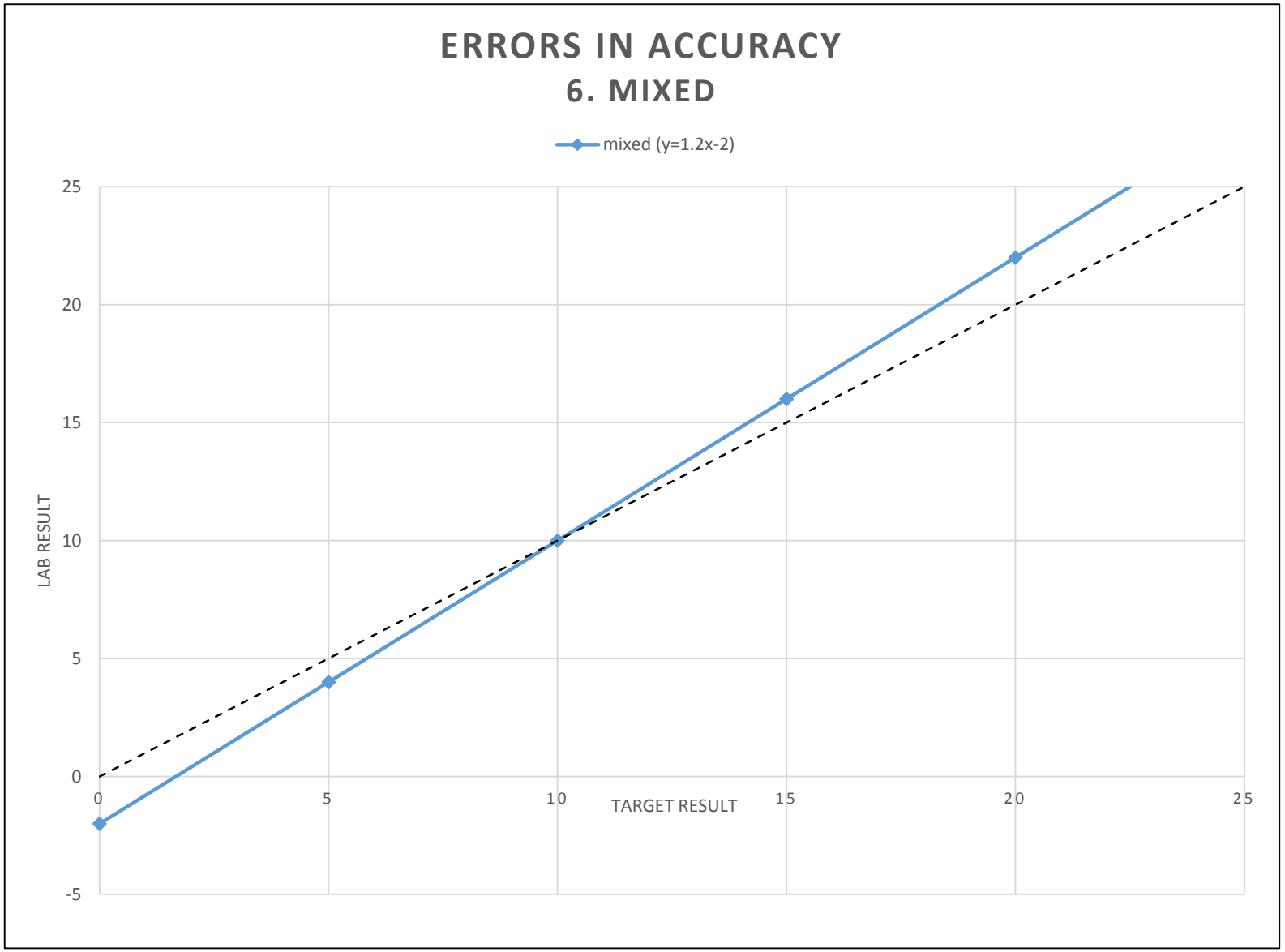
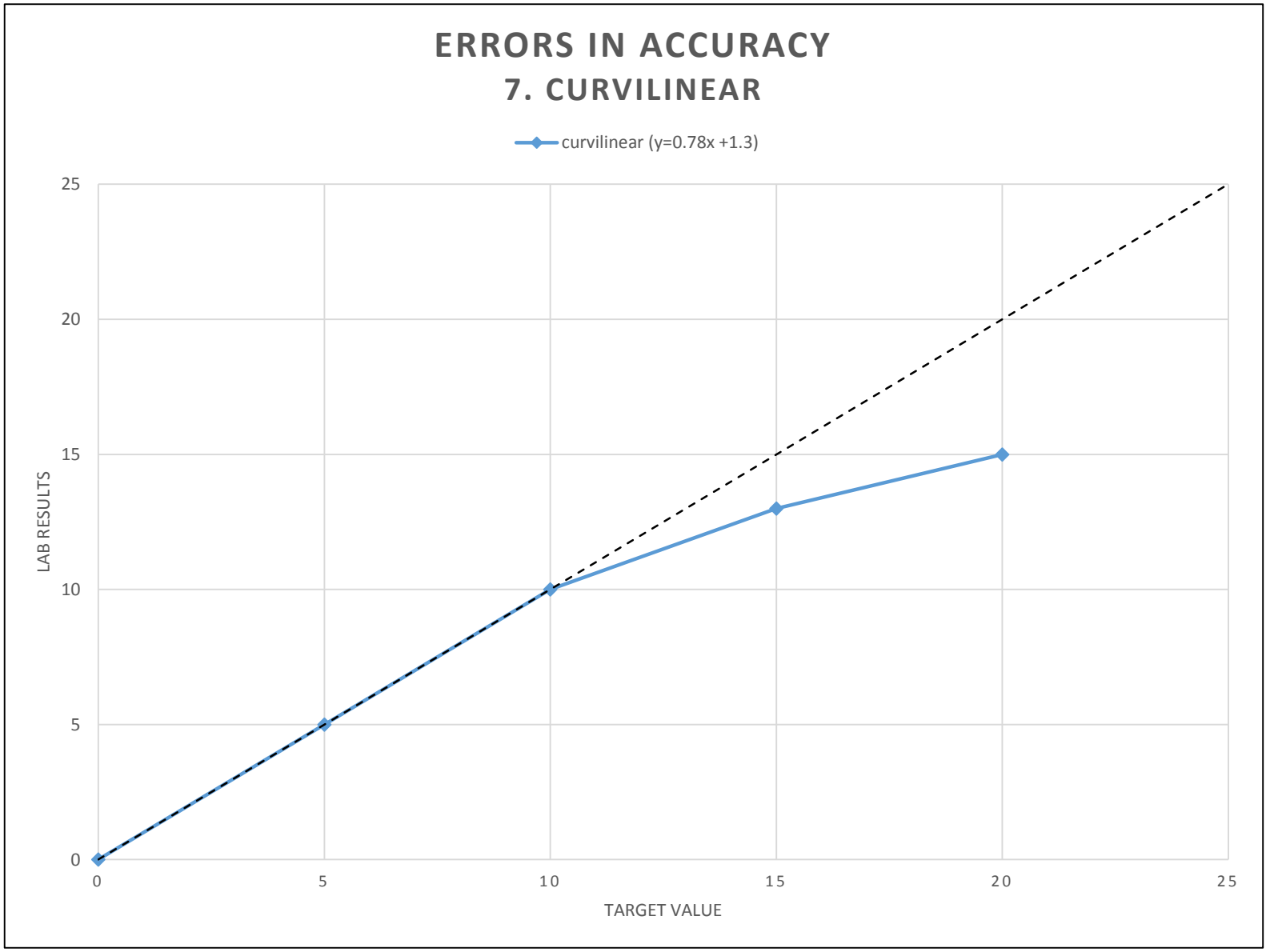

ERRORS IN ACCURACY
6. MIXED
mixed (y=1.2x-2)
25
20
15
10
5
0
-5
LAB RESULT
0
5
10
15
20
25
TARGET RESULT

Weqas

ERRORS IN ACCURACY

7. CURVILINEAR



Weqas

Types of Errors

	Imprecision		Inaccuracy		
	Random	Curvilinear	Prop	Mixed	Constant
Slope	No	Yes/No	Yes	Yes	No
Intercept	No	Yes/No	No	Yes	Yes
Sy,x	Yes	Yes	No	No	No
r	Yes	Yes	No	No	No

Analyte detailed report

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	Uncert.	6.950	6.903	12.083	13.512	27.204	0.545	
Overall	Mean	282.70	163.62	347.38	359.41	1083.57	69.54	
	SD	22.83	12.82	22.16	33.15	50.95	3.90	
	Number	19	18	18	19	18	10	
	Uncert.	5.237	3.022	5.224	7.606	12.009	1.233	
Reference Values ID-LC-MS/MS		298.36	177.20	356.88	377.36	1065.45		
Ref. Value Uncertainty		6.100	3.600	7.300	7.700	21.800		
Non-scoring Reference Values								
WeQas SD		30.30	18.19	36.87	38.10	111.75	8.62	
SDI		**0.18**	**0.36**	**0.17**	**0.28**	**-0.18**	**0.29**	**0.24**

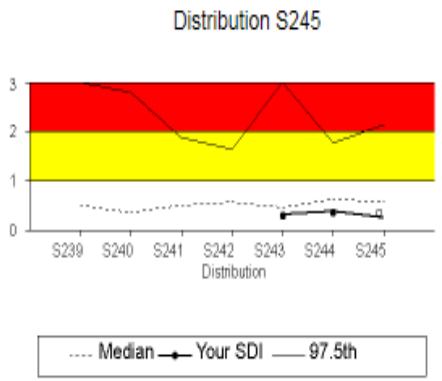
Please note: Linear regression uses CF corrected data.

Total Error

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

This Distribution S245
Your average analyte SDI for the 6 samples is 0.24

Previous SDI



Ref Values used for SDI and Sigma Scoring

Performance Criteria Target

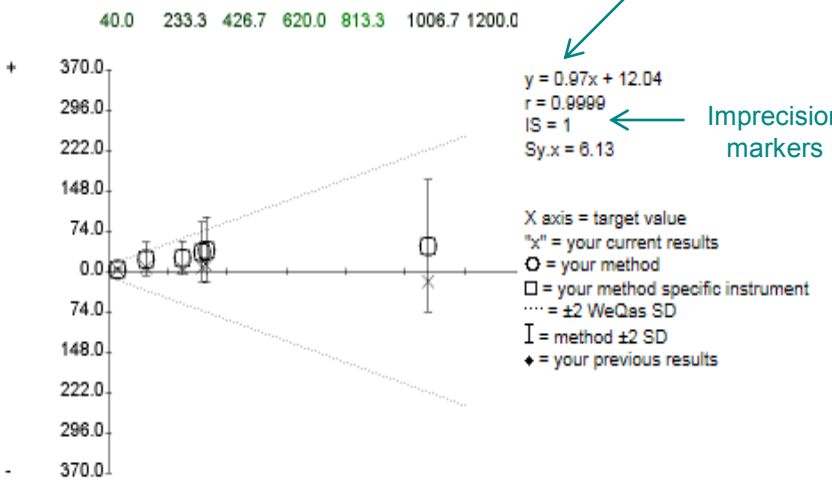
SDI Score

Weqas

Analyte detailed report

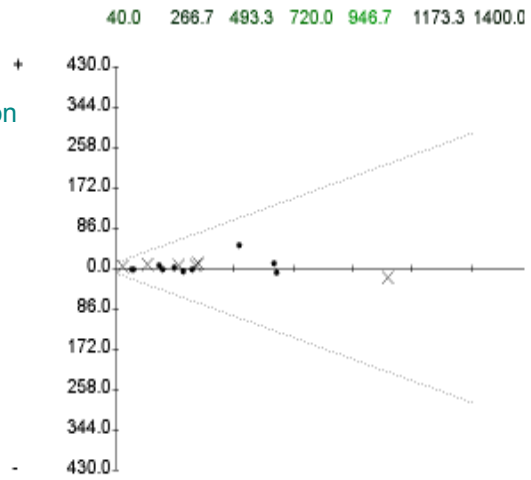
This Distribution *S245*

Linear Regression Equation



Imprecision markers

Previous Distributions



Precision

This Distribution S245	Previous Distributions	S244	S243	S242	S241	S240	S239
Sy.x = 6.13 nmol/L IS = 1	**Sy.x**	4.46	27.15				
	IS	2	53	0	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 S245	Previous Distributions	S244	S243	S242	S241	S240	S239
Systematic proportional error (calibration) -2.61% Systematic constant error (blank) 12.04 nmol/L	**Proportional (%)**	2.11	3.08				
	Constant (nmol/L)	- 14.46	- 5.24	0.00	0.00	0.00	0.00

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.

Current slope and intercept
y = 0.97x + 12.04

Previous slope and intercept values

Weqas

Problem Solving Flow Chart

START HERE

IMPRECISION

[1]

Are you satisfied with your imprecision values? (Sy.x, r)

YES →

INACCURACY

[2]

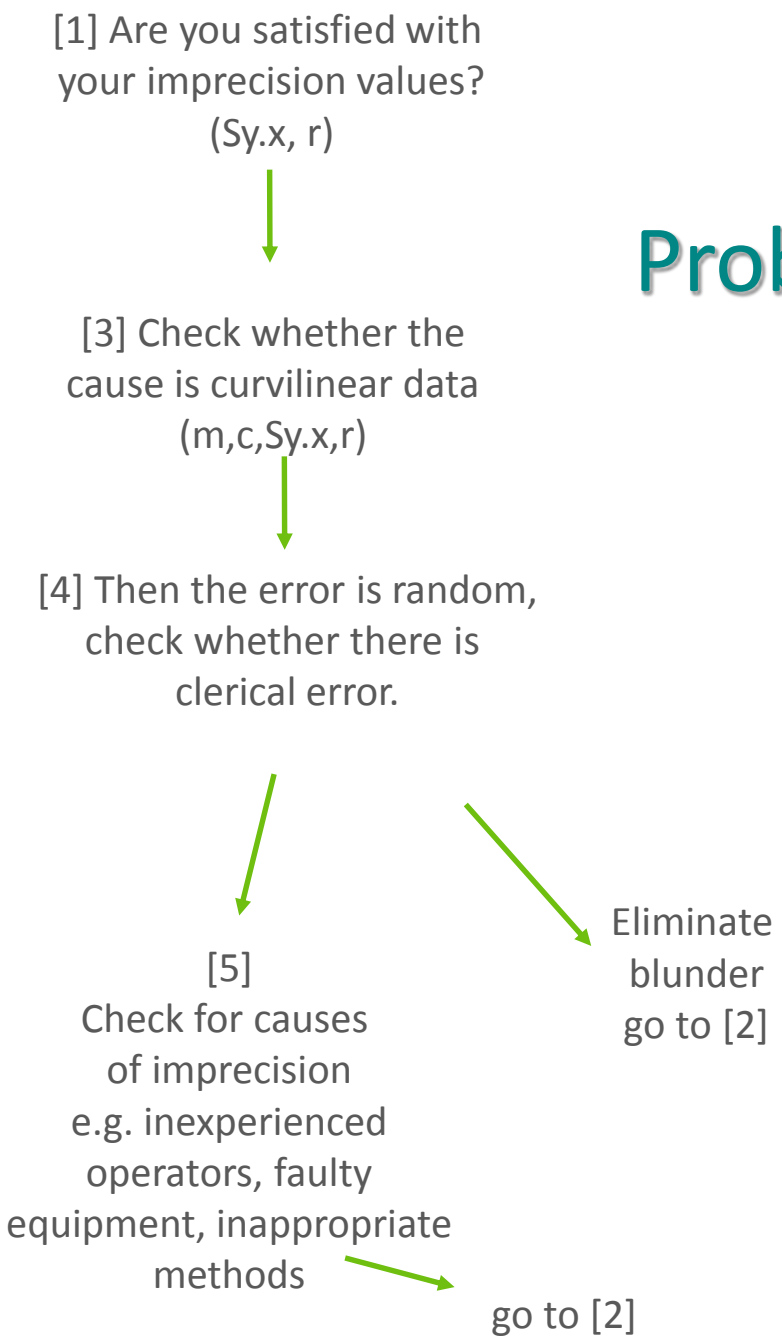
Are you satisfied with slope and intercept? (m, c)

YES →

Weqas

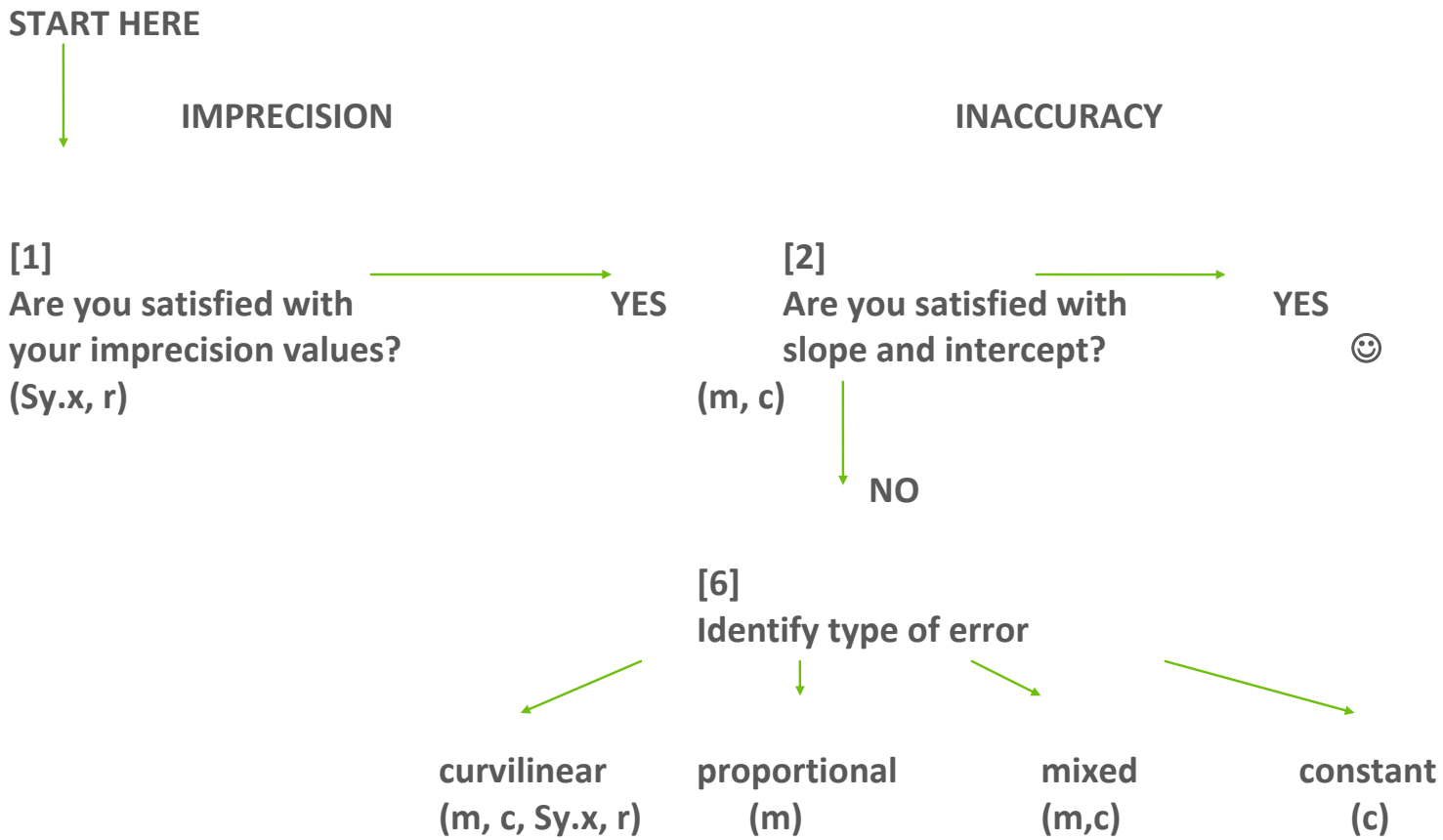
Problem Solving Flow Chart

IMPRECISION



Weqas

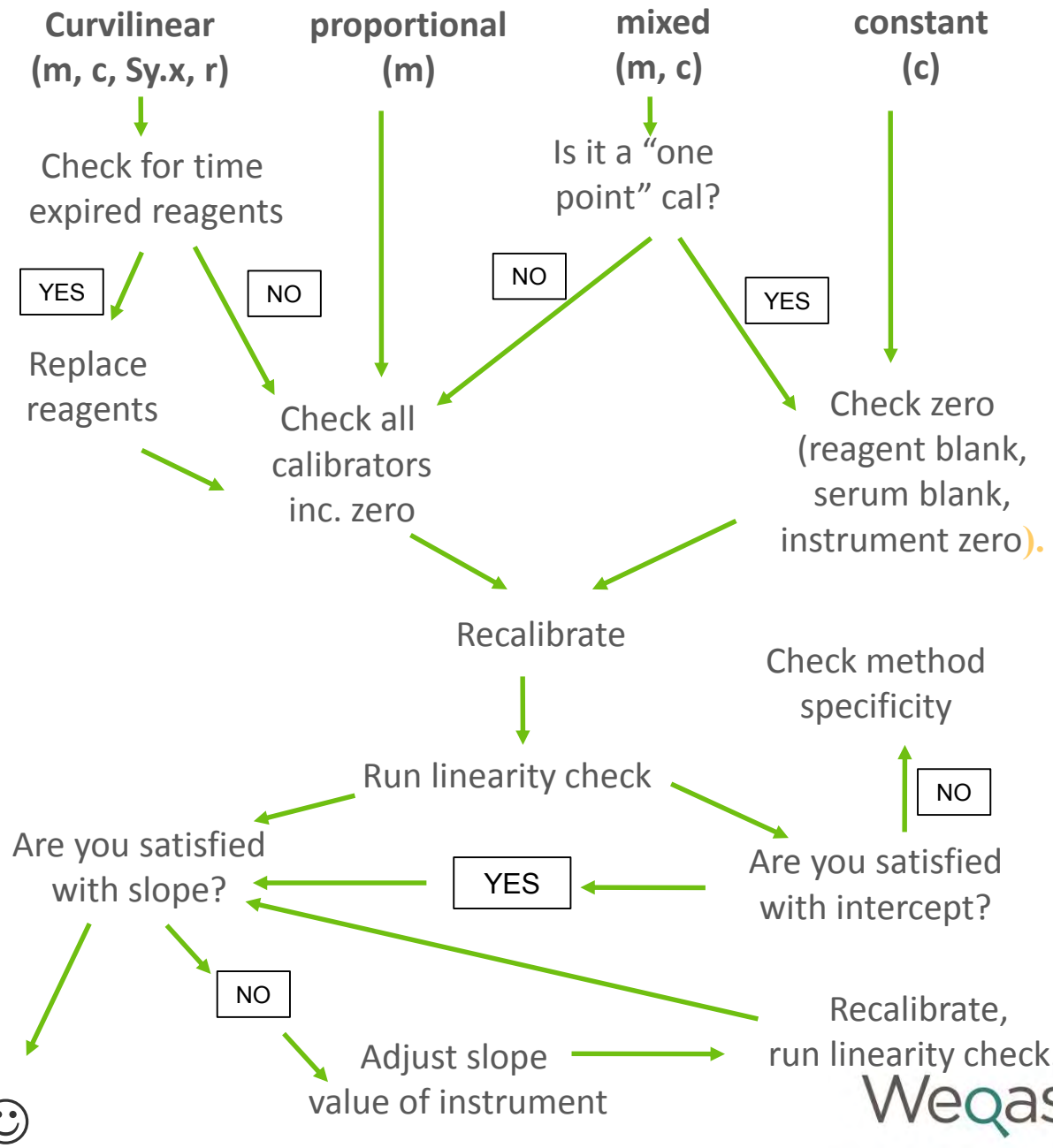
Problem Solving Flow Chart



Weqas

Problem Solving Flow Chart

INACCURACY



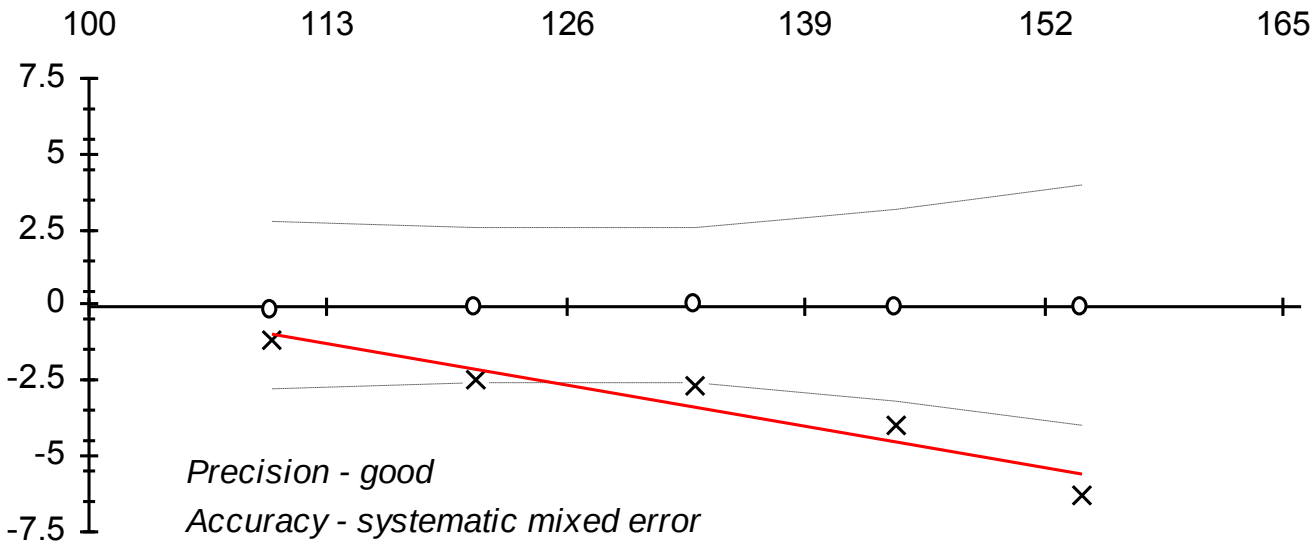
Problem Solving checklist

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

Weqas

Bias plot (1)

Sodium (mmol/l)

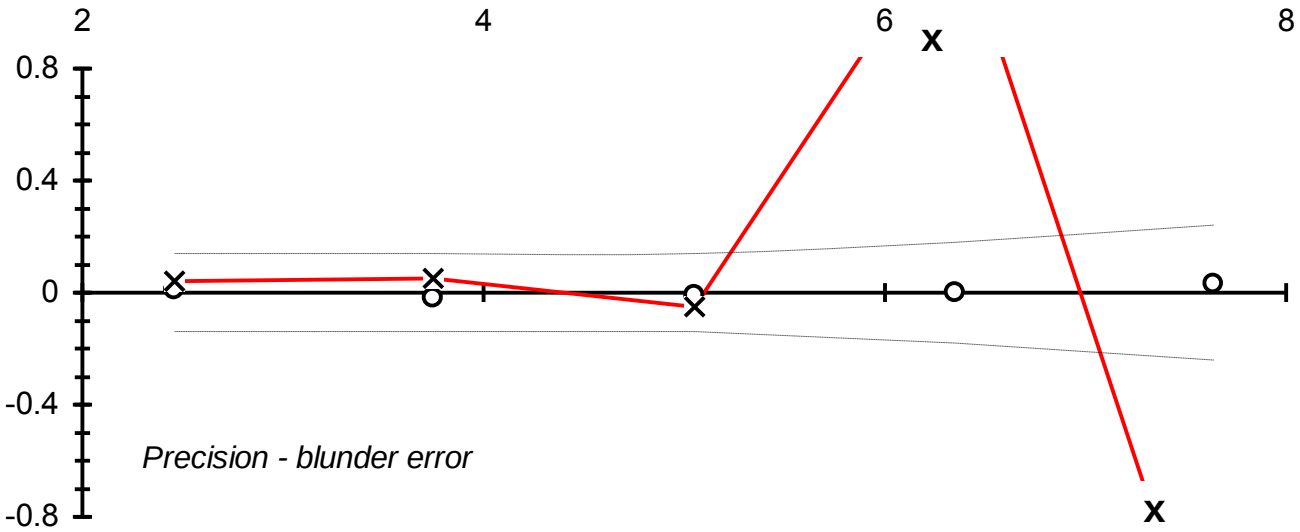


y = 0.9 x + 9.6
r= 0.9995
IS= 5
Sy.x= 0.63

Weqas

Bias plot (2)

Potassium (mmol/l)

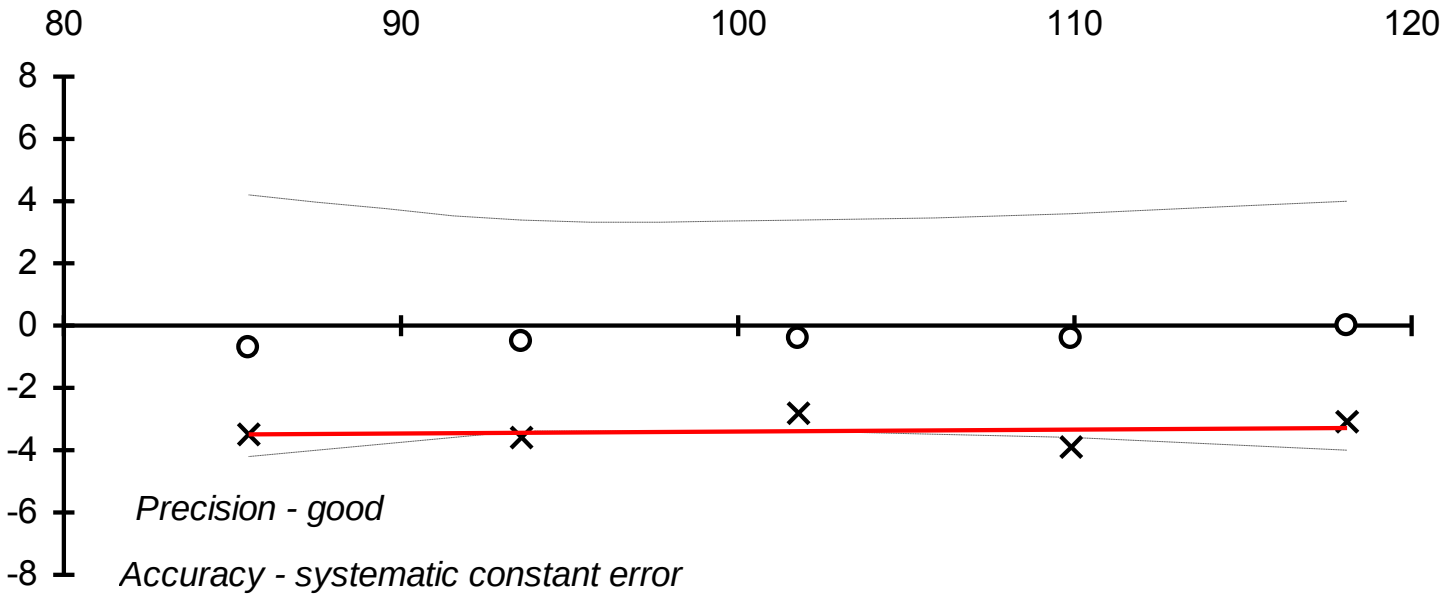


y = slope not calculated
r = 0.8826
IS = 1174
Sy.x= 1.10

Weqas

Bias plot (3)

Chloride (mmol/l)

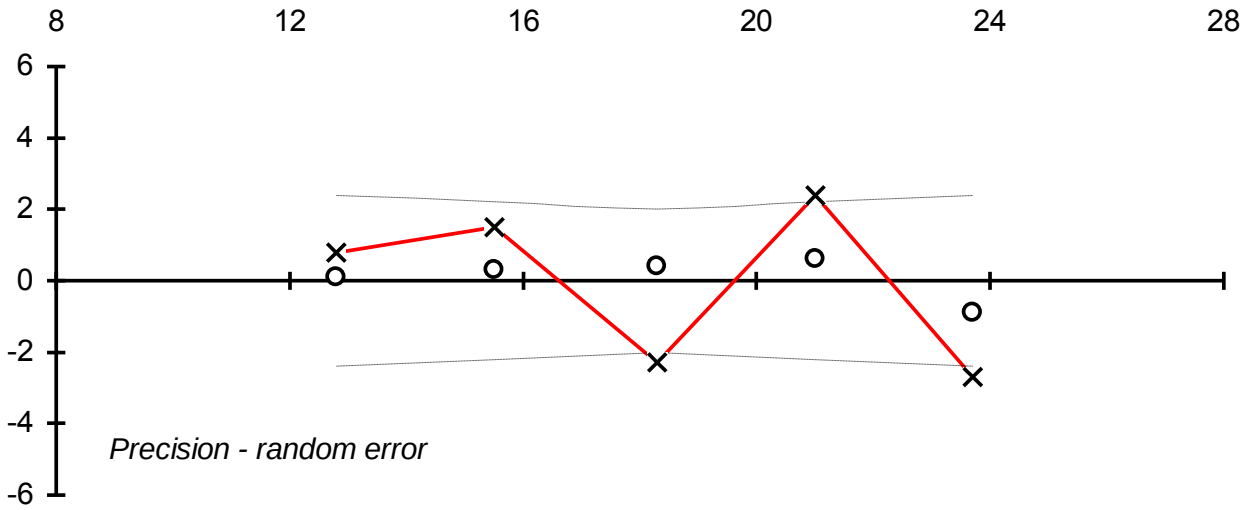


y =1.01x -4.01
r = 0.9995
IS = 5
Sy.x= 0.49

Weqas

Bias plot (4)

Bicarbonate (mmol/l)



y = slope not calculated

r = 0.8484

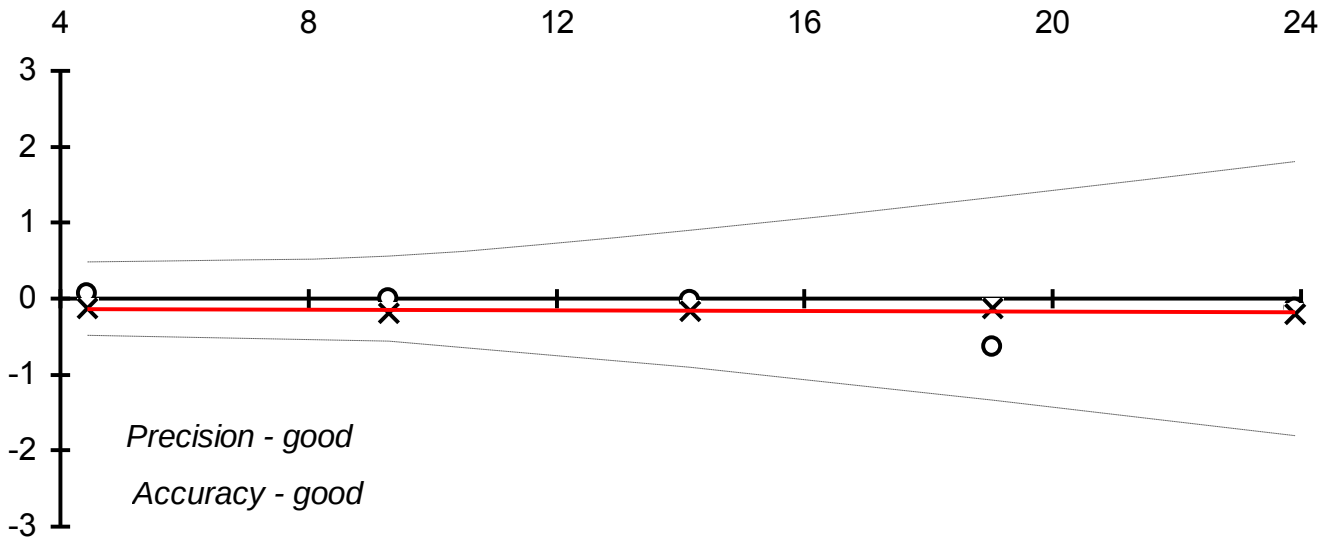
IS = 1516

Sy.x= 2.41

Weqas

Bias plot (5)

Urea (mmol/l)

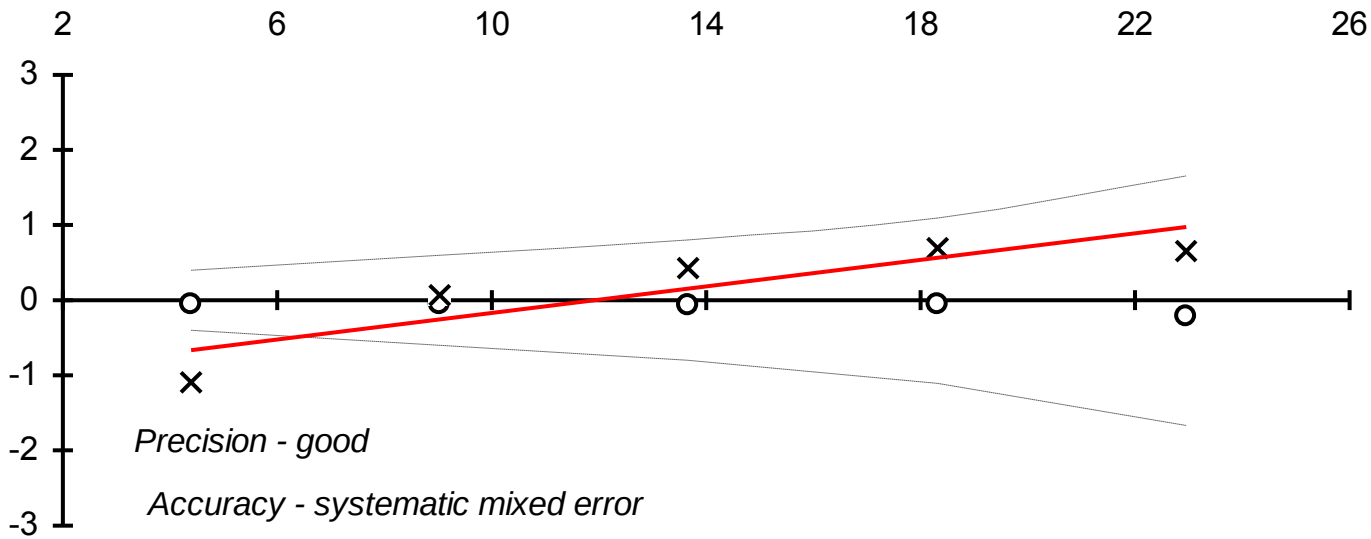


y = 1.00x -0.14
r = 1.000
IS = 0
Sy.x= 0.03

Weqas

Bias plot (6)

Glucose (mmol/l)

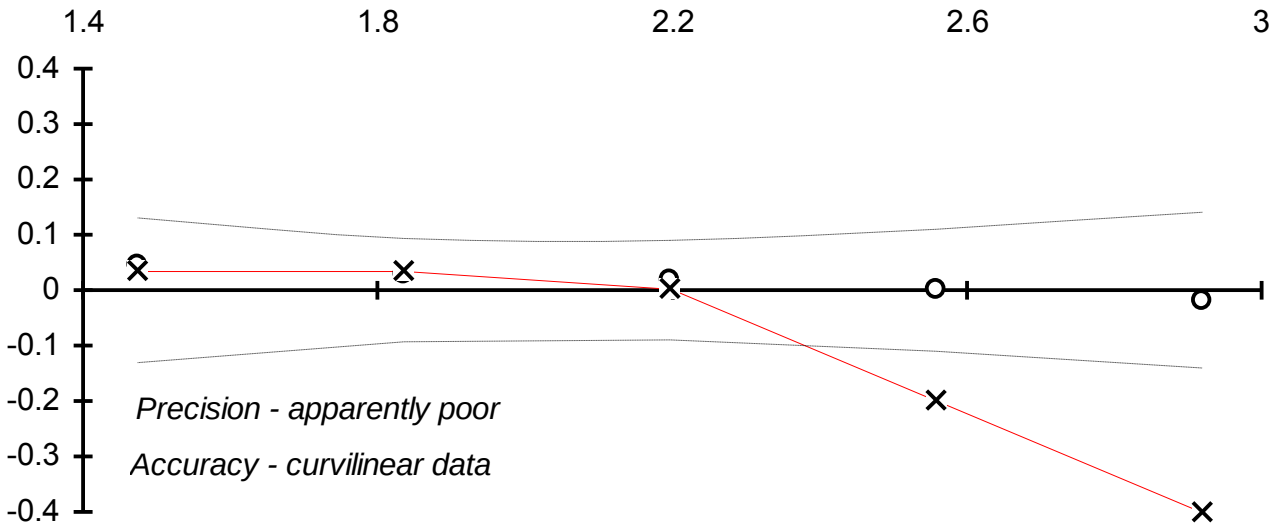


y = 1.09x -1.06
r = 0.9991
IS = 9
Sy.x= 0.40

Weqas

Bias plot (7)

Calcium (mmol/l)



y = slope not calculated

r = 0.9810

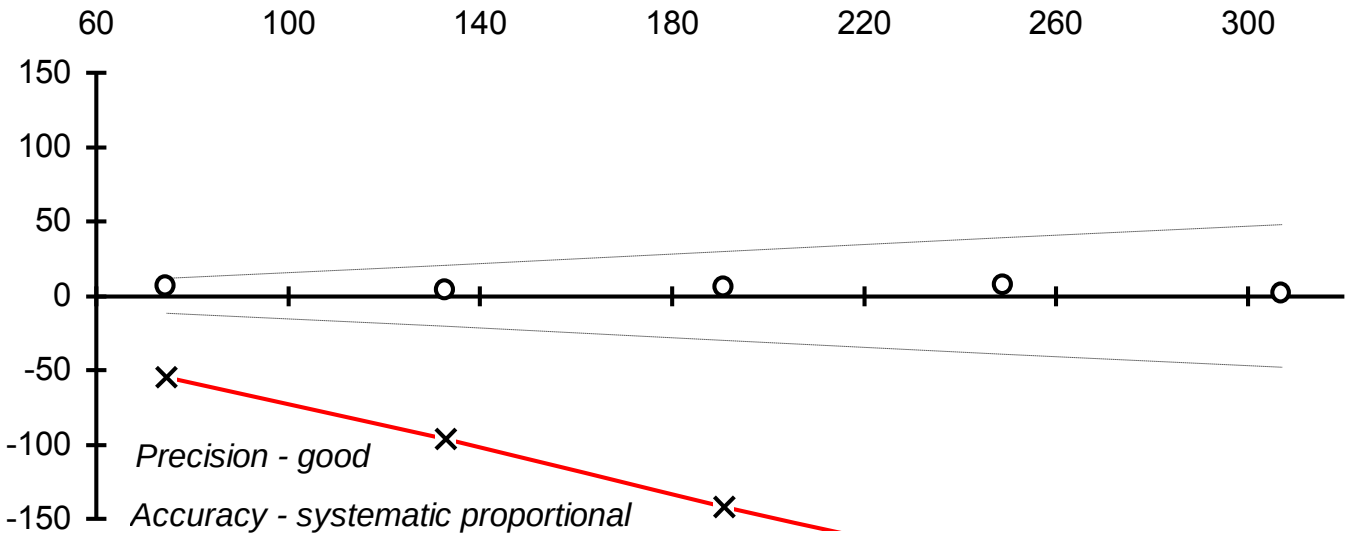
IS = 190

Sy.x= 0.09

Weqas

Bias plot (8)

ALP (IU/L)



y = 0.50 x +1.16
r = 0.9999
IS = 1
Sy.x=1.30

Weqas