Weqas
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Weqas | GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

REFERENCE MEASUREMENT SERVICES

EDUCATION & TRAINING

EQA Report Interpretation

Gareth Davies / Sam Jones

Overview

- Why multiple samples are important
- The Weqas Report - Statistical Indices
  - Imprecision
  - Inaccuracy
- How do we set Analytical Performance Specifications (APS) and Target Values
- Weqas Connect Reports
- Problem Solving and Cases
- Case Study Example

Why multiple samples are important

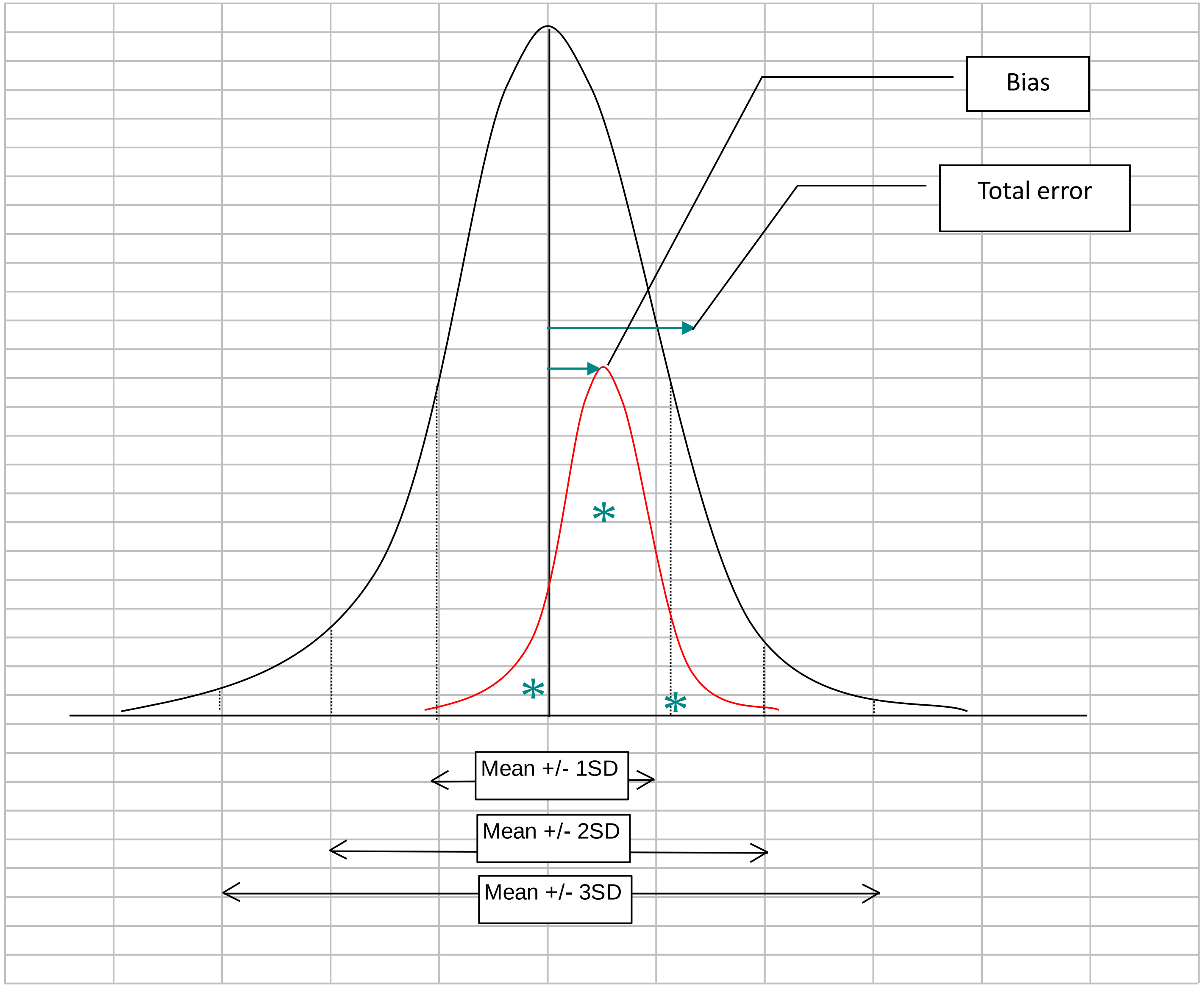
Identifies components of both Imprecision and Inaccuracy

Identifies systematic errors

Assesses method linearity – required for ISO 15189

Powerful error detection tool

Gaussian Distribution



The Weqas Report
Statistical Indices

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

Interpretation of Imprecision

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 imprecision. This is given in the units of the analyte in question.

Correlation coefficient (**r value**) is also an index of within run imprecision. 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).

'r' value	Imprecision score		
0.9990 to 1.0000	0 to 10	-	Good
0.9850 to 0.9989	11 to 150	-	Acceptable to Warning level
< 0.9850	> 150	-	Unacceptable (including Curvilinear Data)

Imprecision indices

Standard deviation

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

where
y = observed value
ȳ = expected value
d.f. = degrees of freedom

Standard dev of residuals

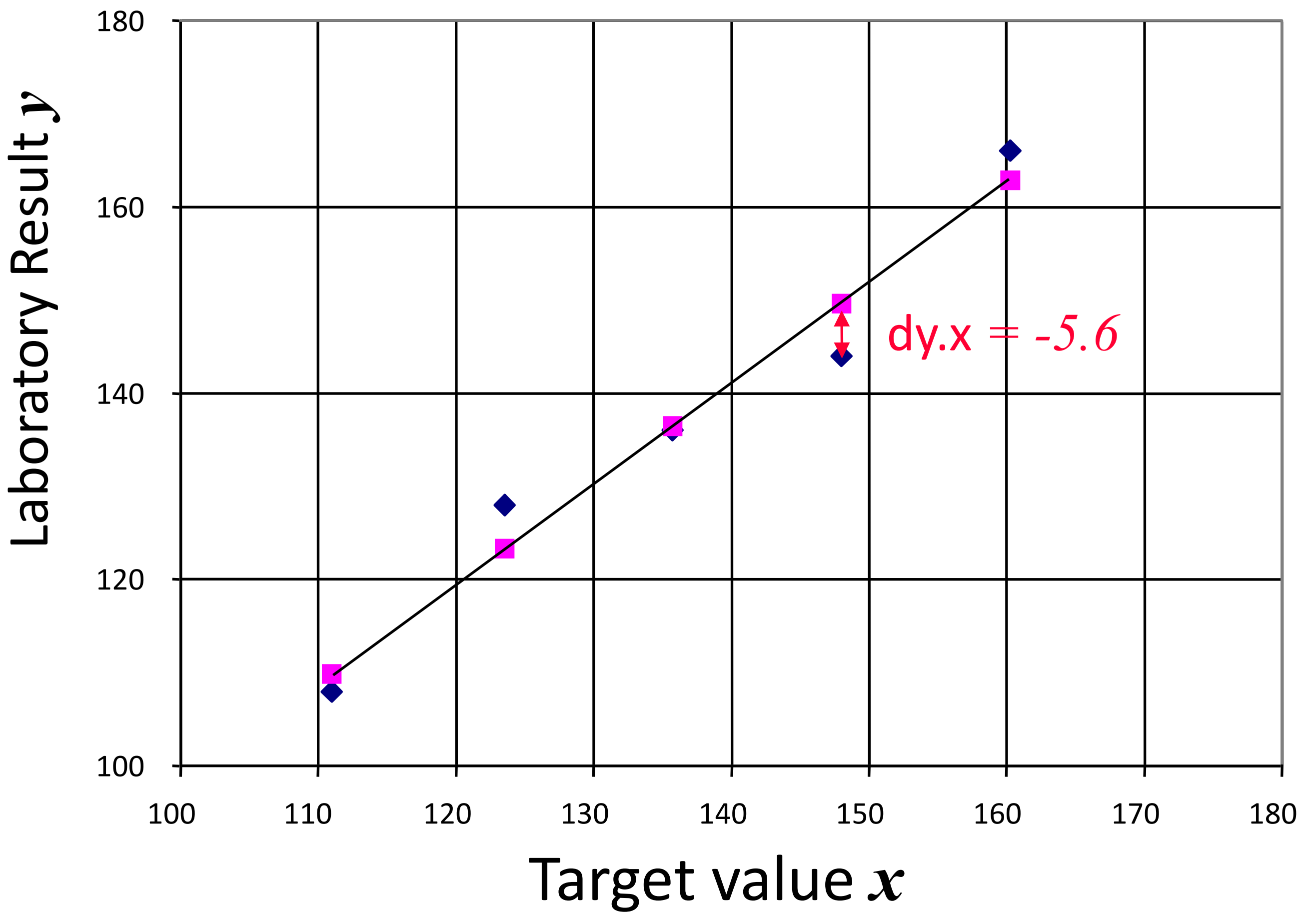
$$\mathrm{Sy.x} = \sqrt{\frac{\Sigma\,(\tilde{y}-y)^2}{\mathrm{d.f.}}}$$

where
ỹ = the value on the line of best fit

Imprecision – Scatter around the “best fit line”, *Sy.x*

Sodium (mmol/l)

Measurement of scatter



■

r = 1.000
Sy.x = 0

All reported results are on the “best fit” line – no scatter

◆

r = 0.9812
Sy.x= 4.1

Reported results are scattered around the “best fit” line – standard deviation of 4.1 mmol/L

Imprecision – how to calculate *Sy.x*

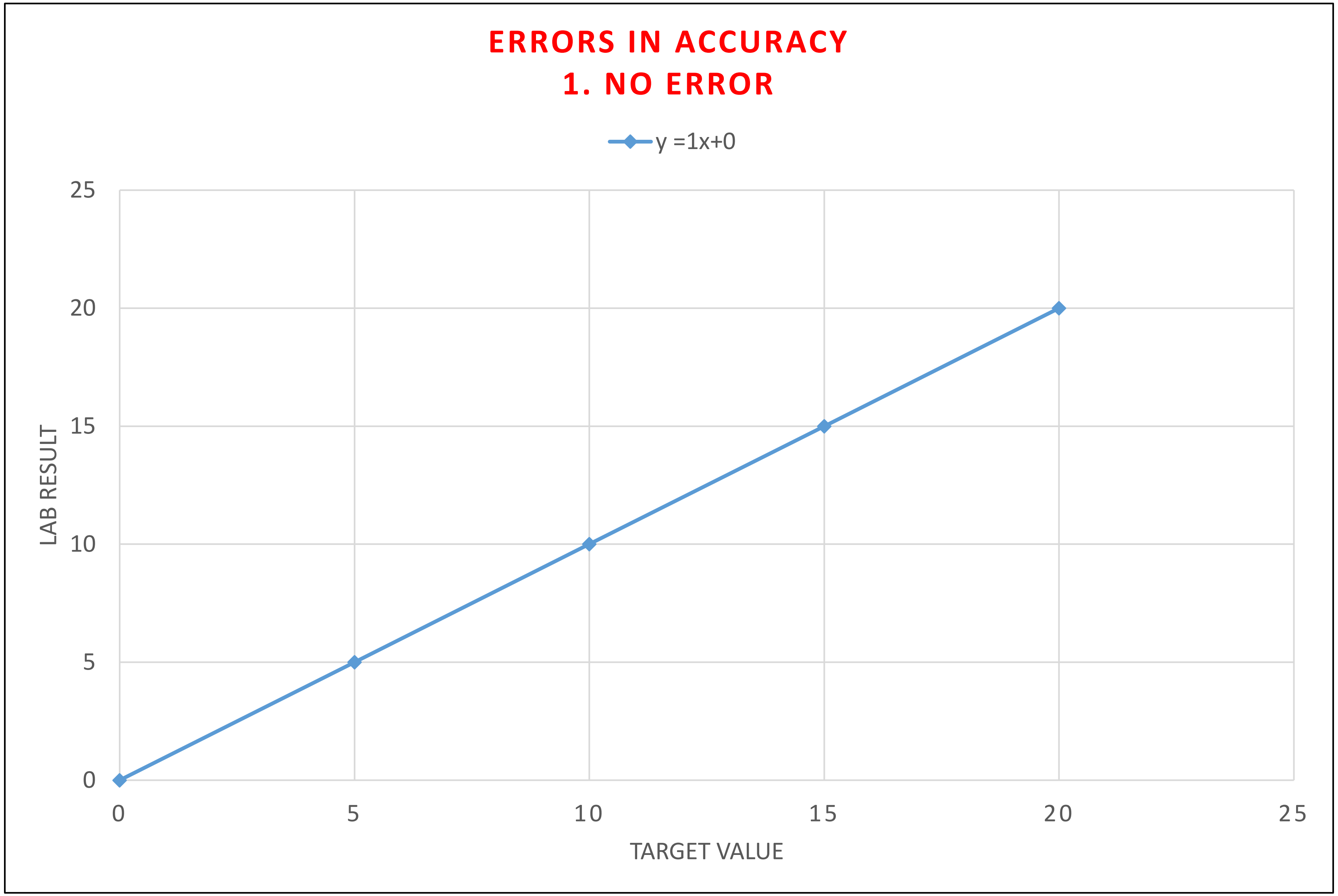
Target value	Lab result	Line of best fit	Deviation	
x	y	$\tilde{y}$	$y-\tilde{y}=dy.x$	$dy.x^2$
111	108	109.9	-1.9	3.62
123.5	128	123.3	4.7	21.97
135.7	136	136.4	-0.4	0.16
148	144	149.6	-5.6	31.30
160.3	166	162.8	3.2	10.31
slope	*1.07*		$\sum dy.x$	$\sum dy.x^2$
int	*-9.17*		0.0	67.36
			$d.f$ = n-1 = 4	
	$S_{y.x}$ =	$\sqrt{\ } \sum dy.x^2/d.f$	$\sqrt{\ }67.4/4$	*4.10*

Interpretation of Inaccuracy

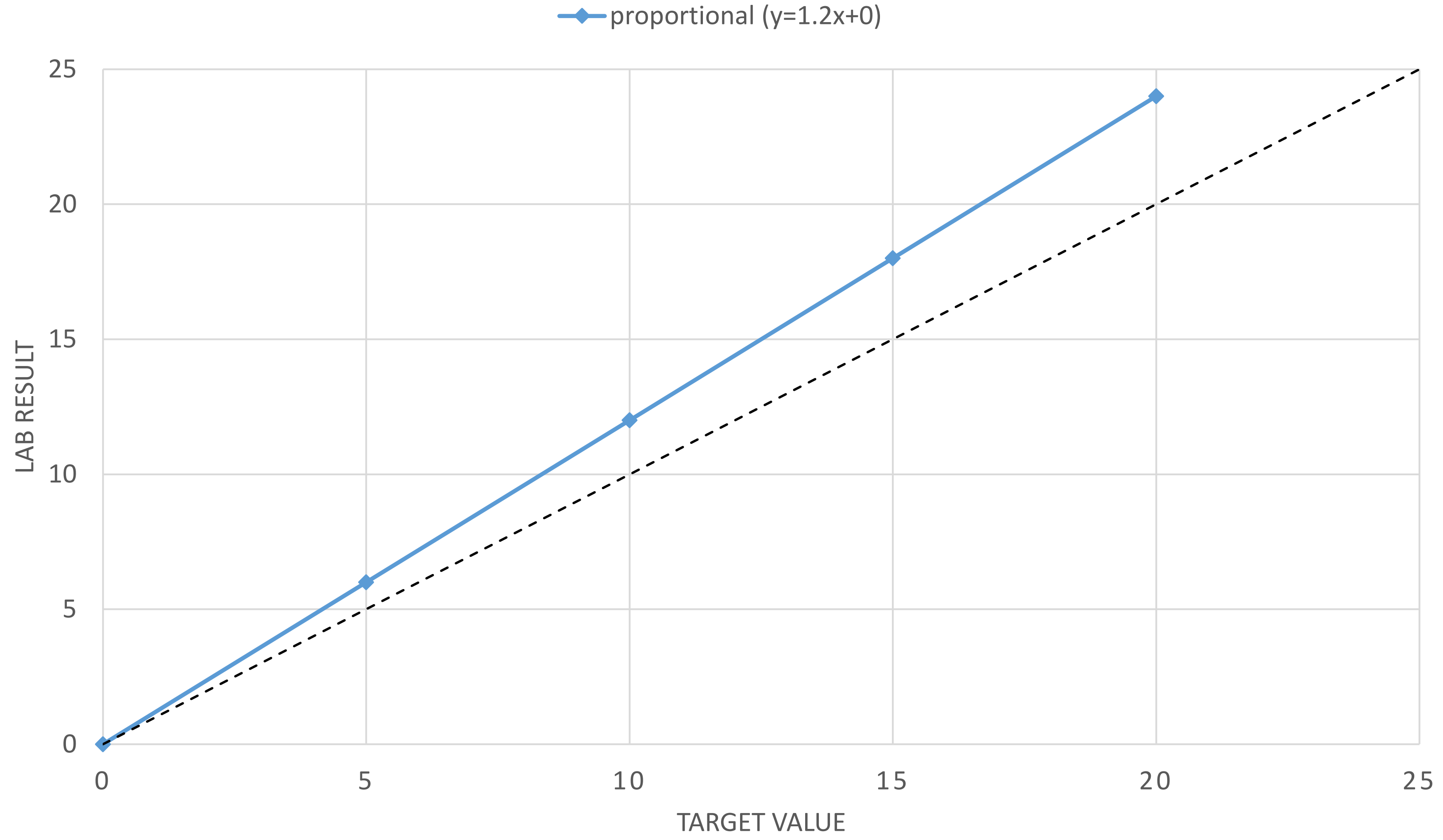
Represents the point at which the line crosses the y axis. This is shown in the units of measurement of each analyte. If deemed significant, this indicates a constant error.

$$y = mx + c$$

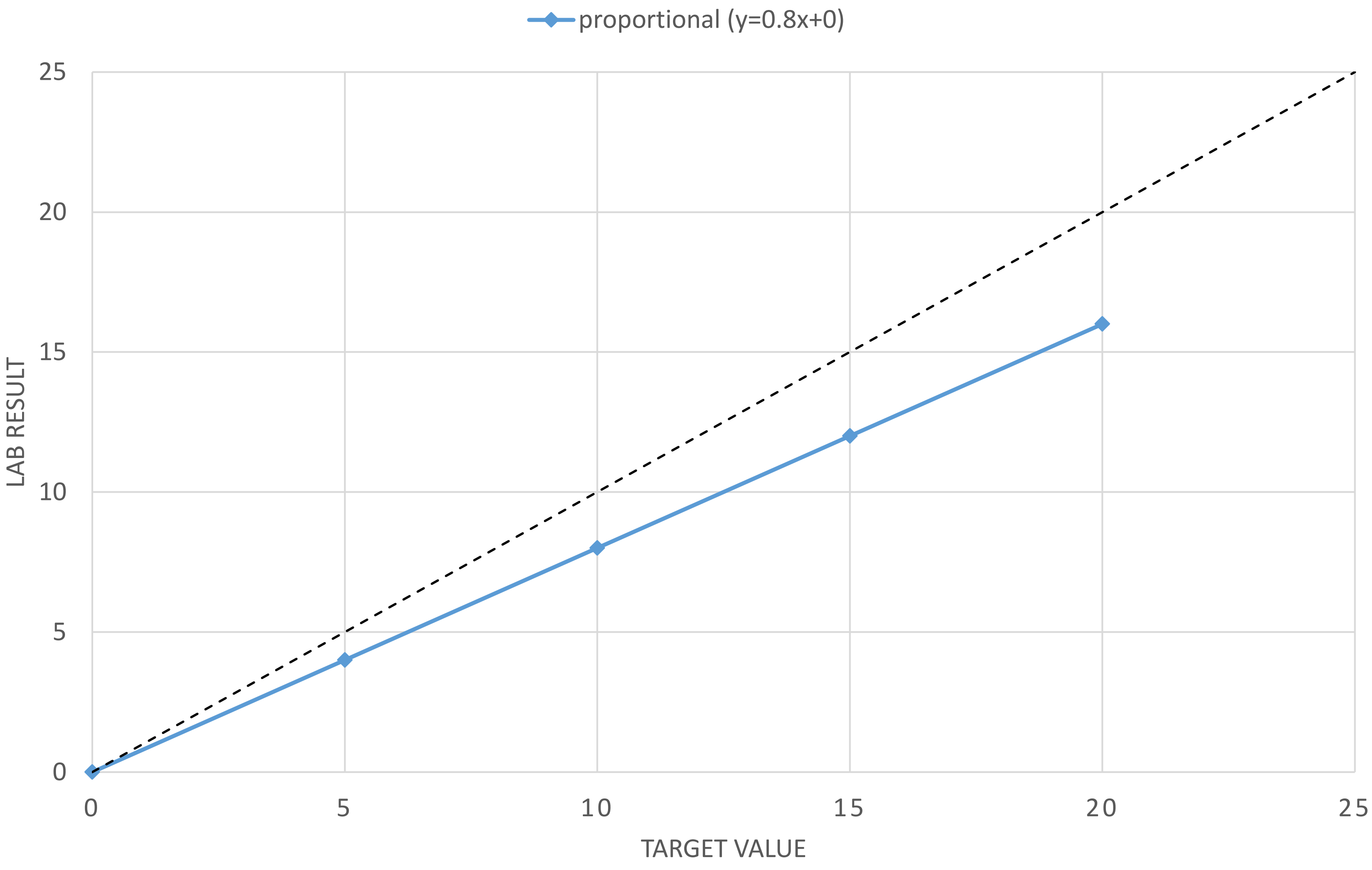
Represents the slope. If deemed significant - indicates a proportional error.


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

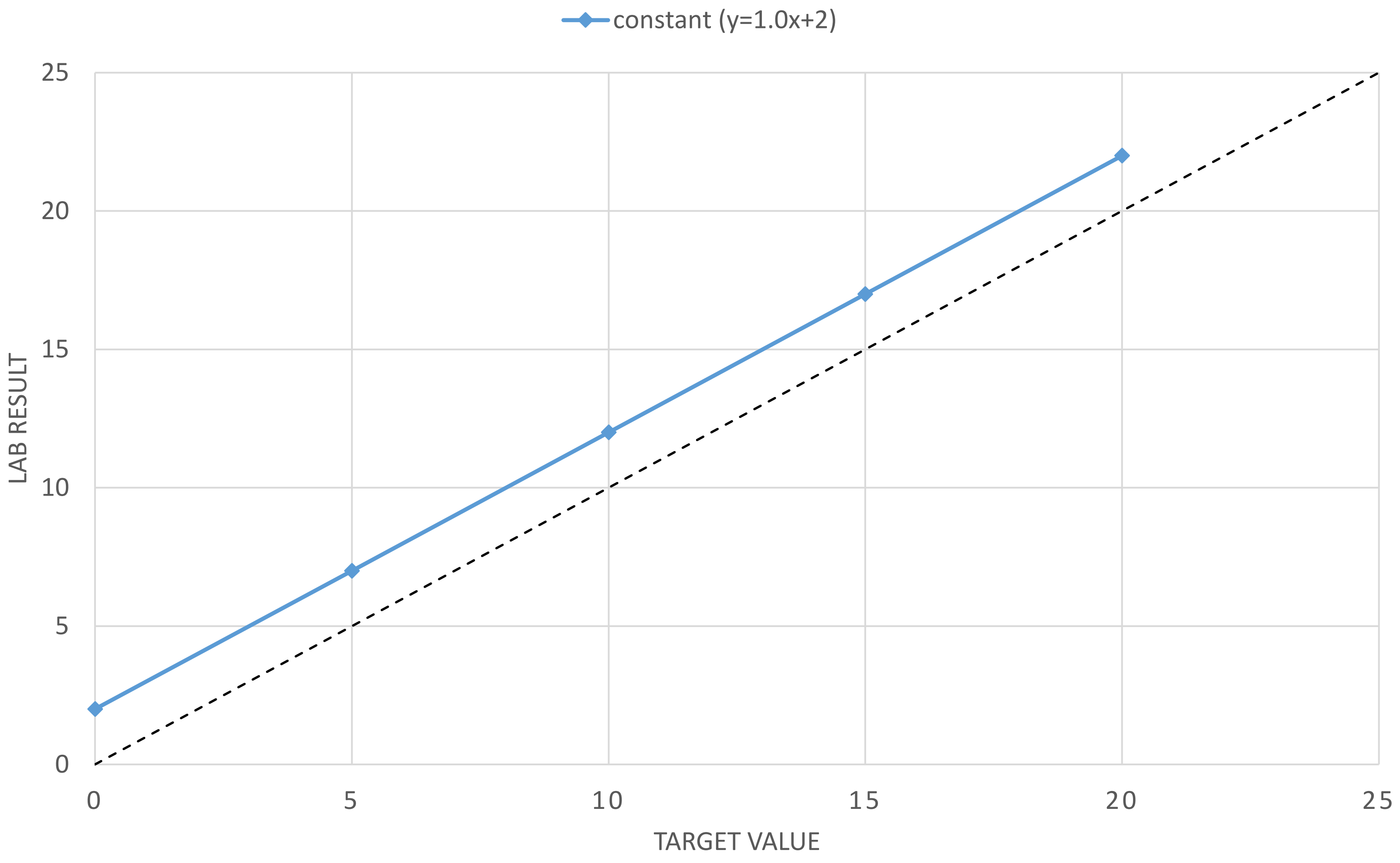
ERRORS IN ACCURACY
2. SYSTEMATIC PROPORTIONAL (POSITIVE BIAS)



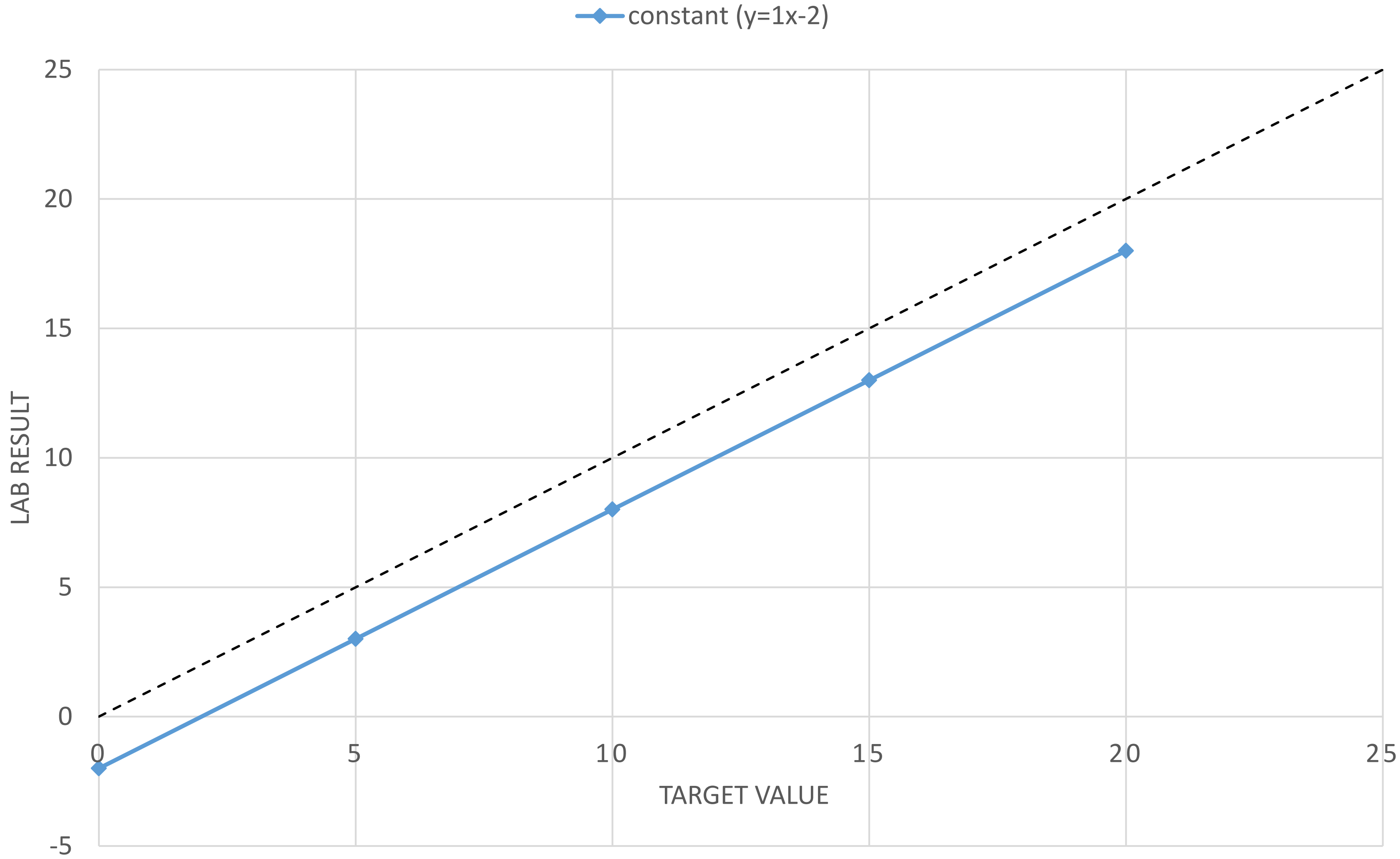
ERRORS IN ACCURACY
3. SYSTEMATIC PROPORTIONAL (NEGATIVE BIAS)

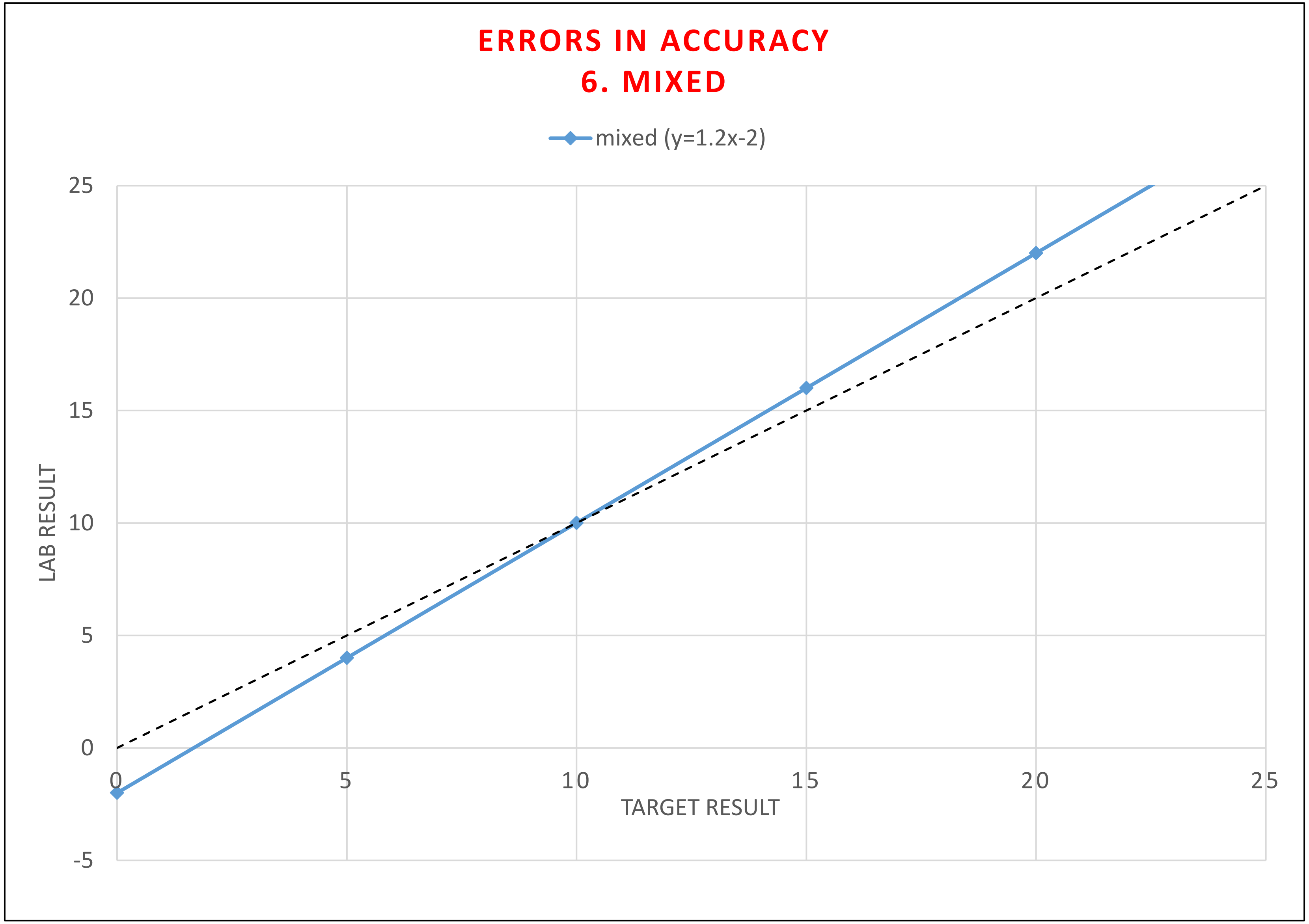


ERRORS IN ACCURACY
4. CONSTANT (POSITIVE BIAS)

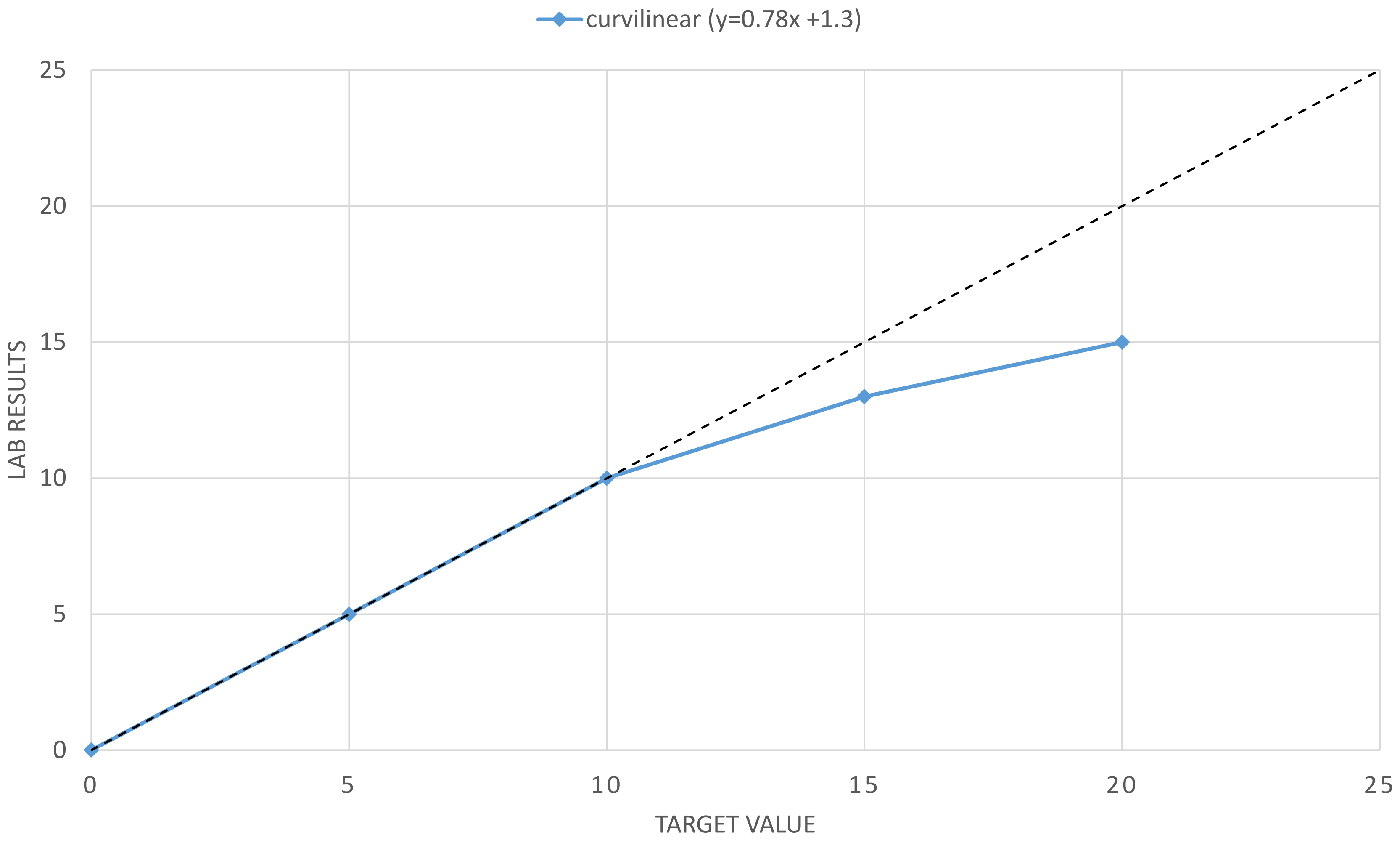


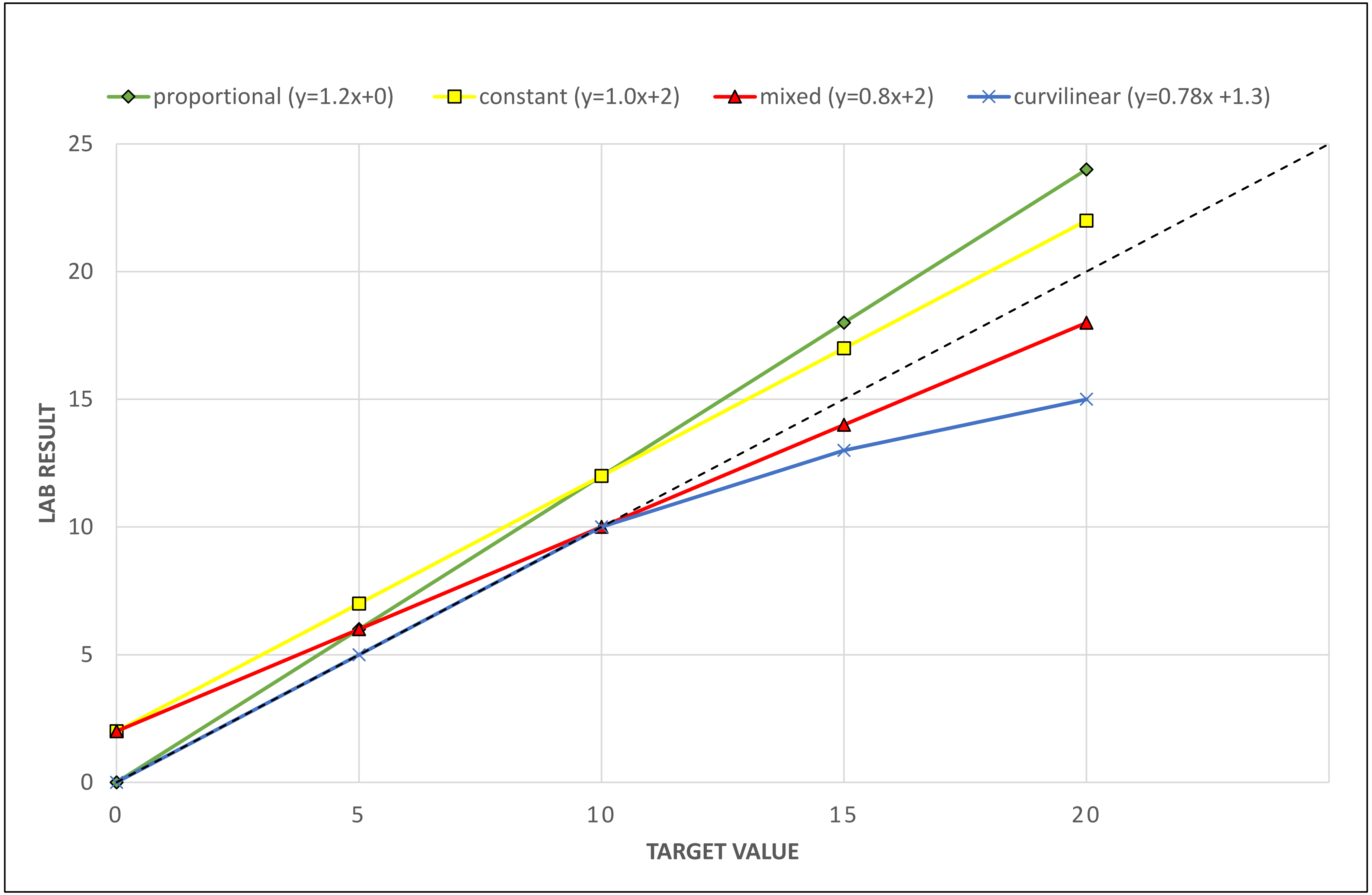
ERRORS IN ACCURACY
5. CONSTANT (NEGATIVE BIAS)




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

ERRORS IN ACCURACY
7. CURVILINEAR





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

	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

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How do we set Analytical Performance Specifications (APS) and Target Values?

The Weqas Report
Target values used in Statistical Analysis

Hierarchy

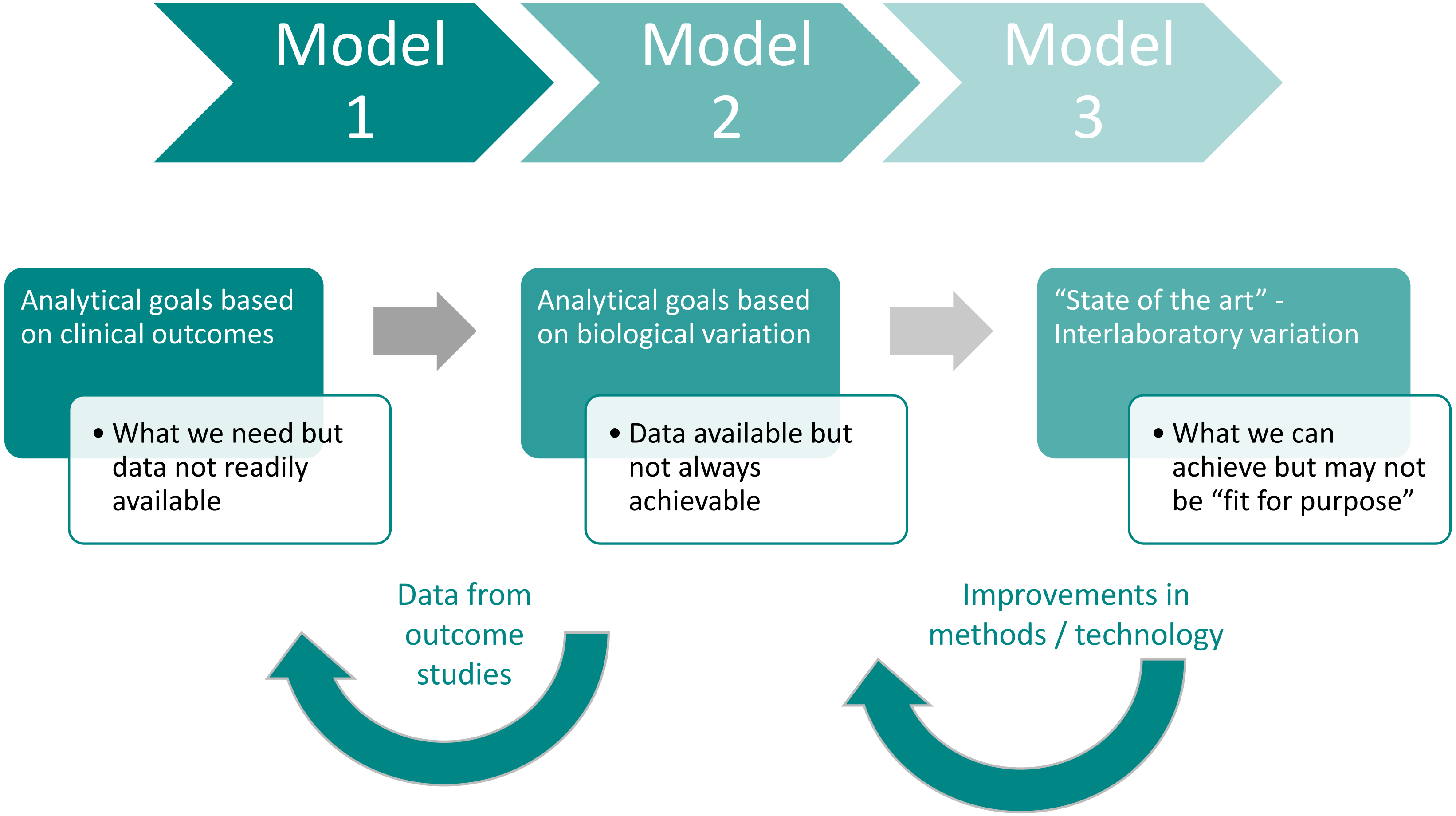
Reference values – used for bias plot & SDI / PI calculation

Method mean – used for SDI / PI calc if no ref value and n≥8

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

Instrument mean – on report for information only

Hierarchy for setting APS



Model 1

Model 2

Model 3

Analytical goals based on clinical outcomes

- What we need but data not readily available

Analytical goals based on biological variation

- Data available but not always achievable

"State of the art" - Interlaboratory variation

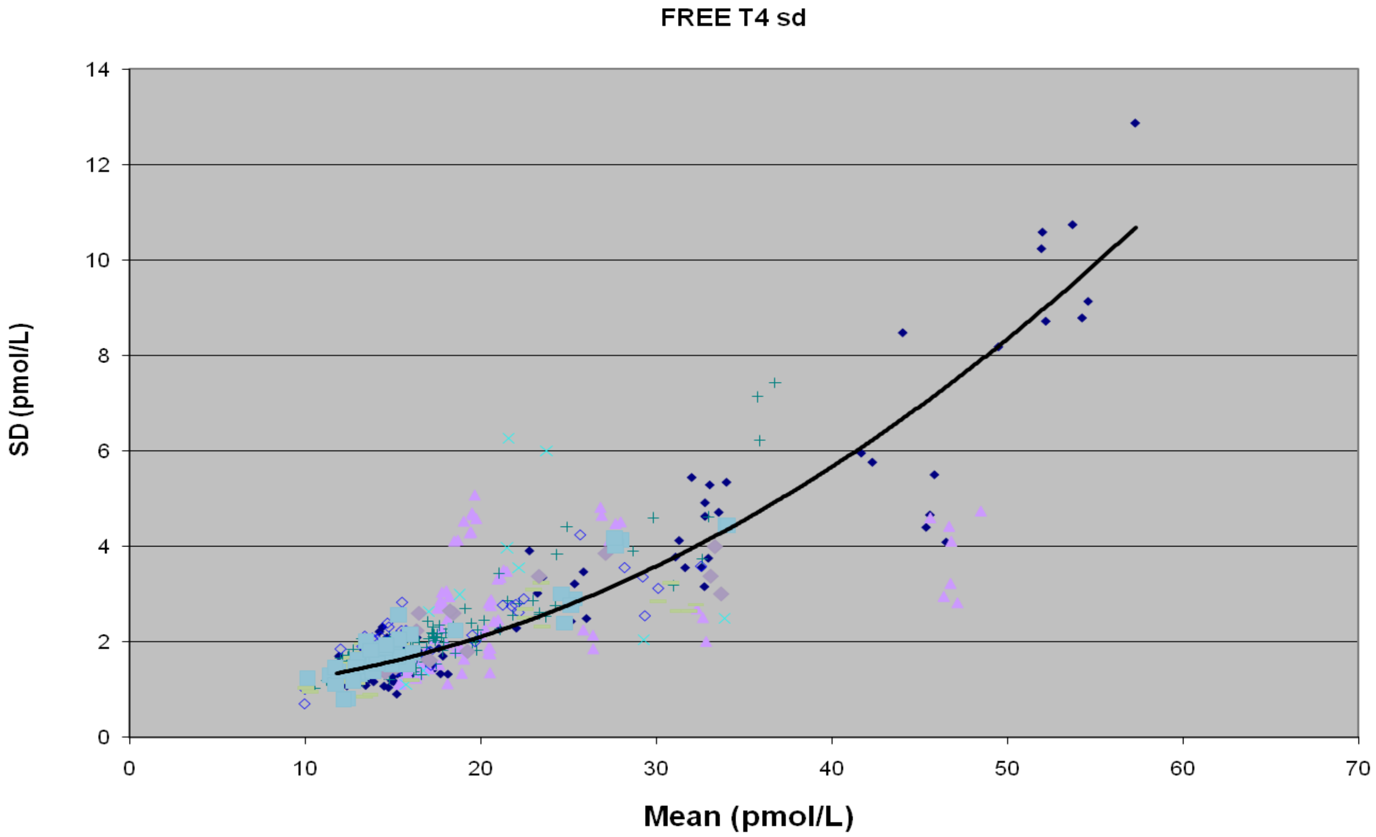
- What we can achieve but may not be "fit for purpose"

Data from outcome studies

Improvements in methods / technology

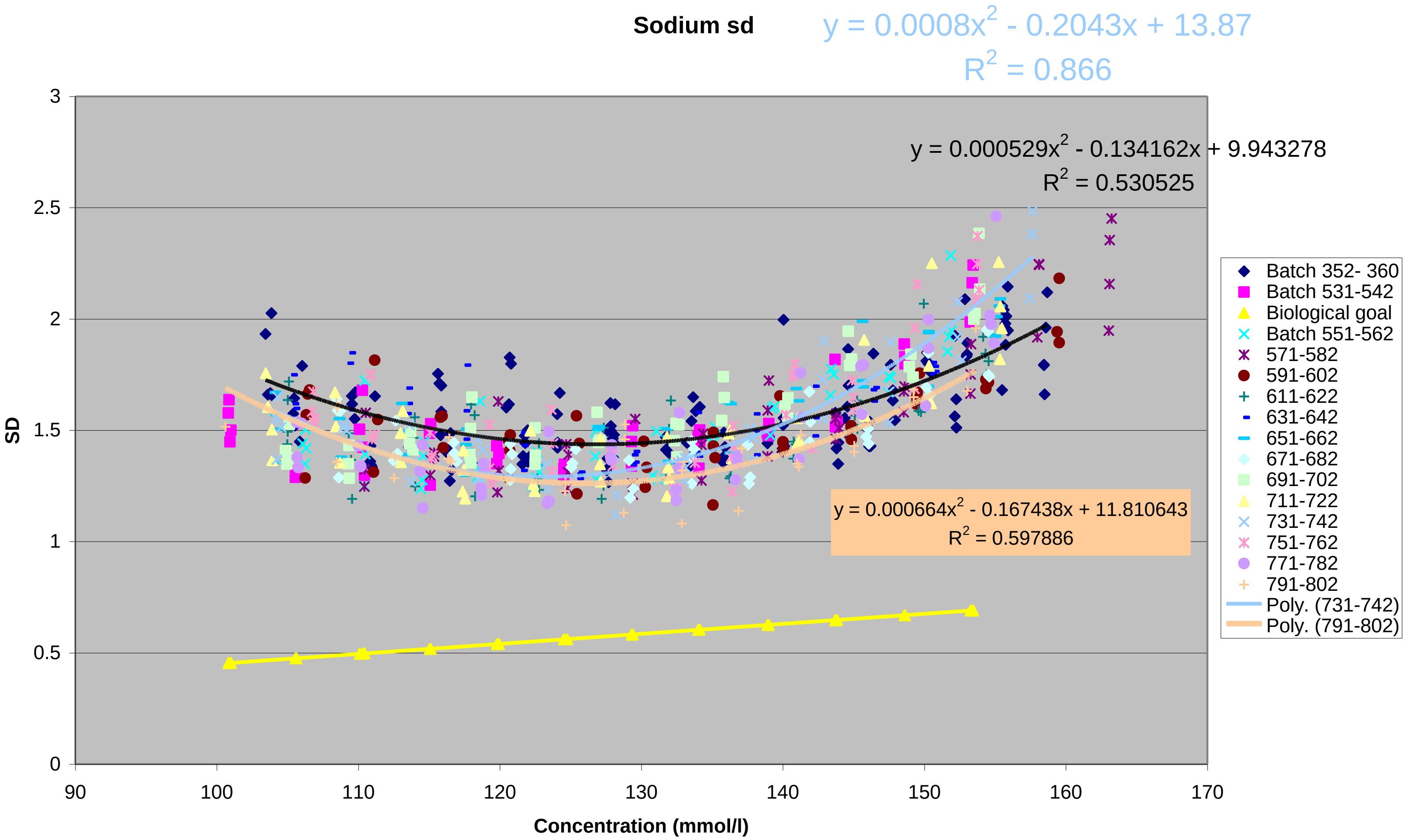
Interlaboratory variation (state of the art)

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

“State of the art” v Biology



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

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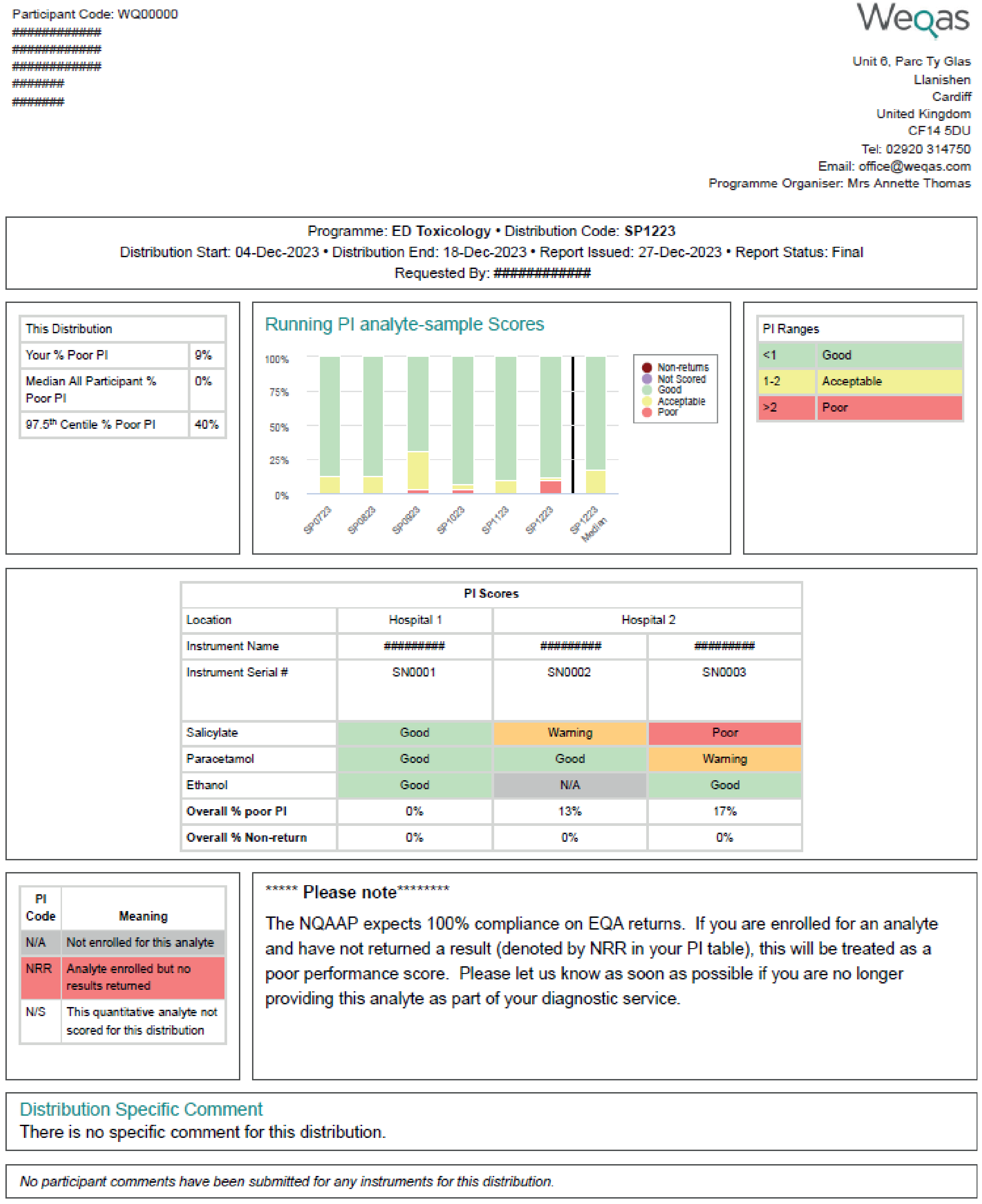
Weqas Connect Reports

Standard Quantitative Report



Participant Code: WQ00000
#############
#############
#############
########
########

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Tel: 02920 314750
Email: office@weqas.com
Programme Organiser: Mrs Annette Thomas

Programme: ED Toxicology • Distribution Code: **SP1223**
Distribution Start: 04-Dec-2023 • Distribution End: 18-Dec-2023 • Report Issued: 27-Dec-2023 • Report Status: Final
Requested By: #############

This Distribution	
Your % Poor PI	9%
Median All Participant % Poor PI	0%
97.5th Centile % Poor PI	40%

Running PI analyte-sample Scores

PI Ranges	
<1	Good
1-2	Acceptable
>2	Poor

PI Scores			
Location	Hospital 1	Hospital 2	
Instrument Name	#########	#########	#########
Instrument Serial #	SN0001	SN0002	SN0003
Salicylate	Good	Warning	Poor
Paracetamol	Good	Good	Warning
Ethanol	Good	N/A	Good
Overall % poor PI	0%	13%	17%
Overall % Non-return	0%	0%	0%

PI Code	Meaning
N/A	Not enrolled for this analyte
NRR	Analyte enrolled but no results returned
N/S	This quantitative analyte not scored for this distribution

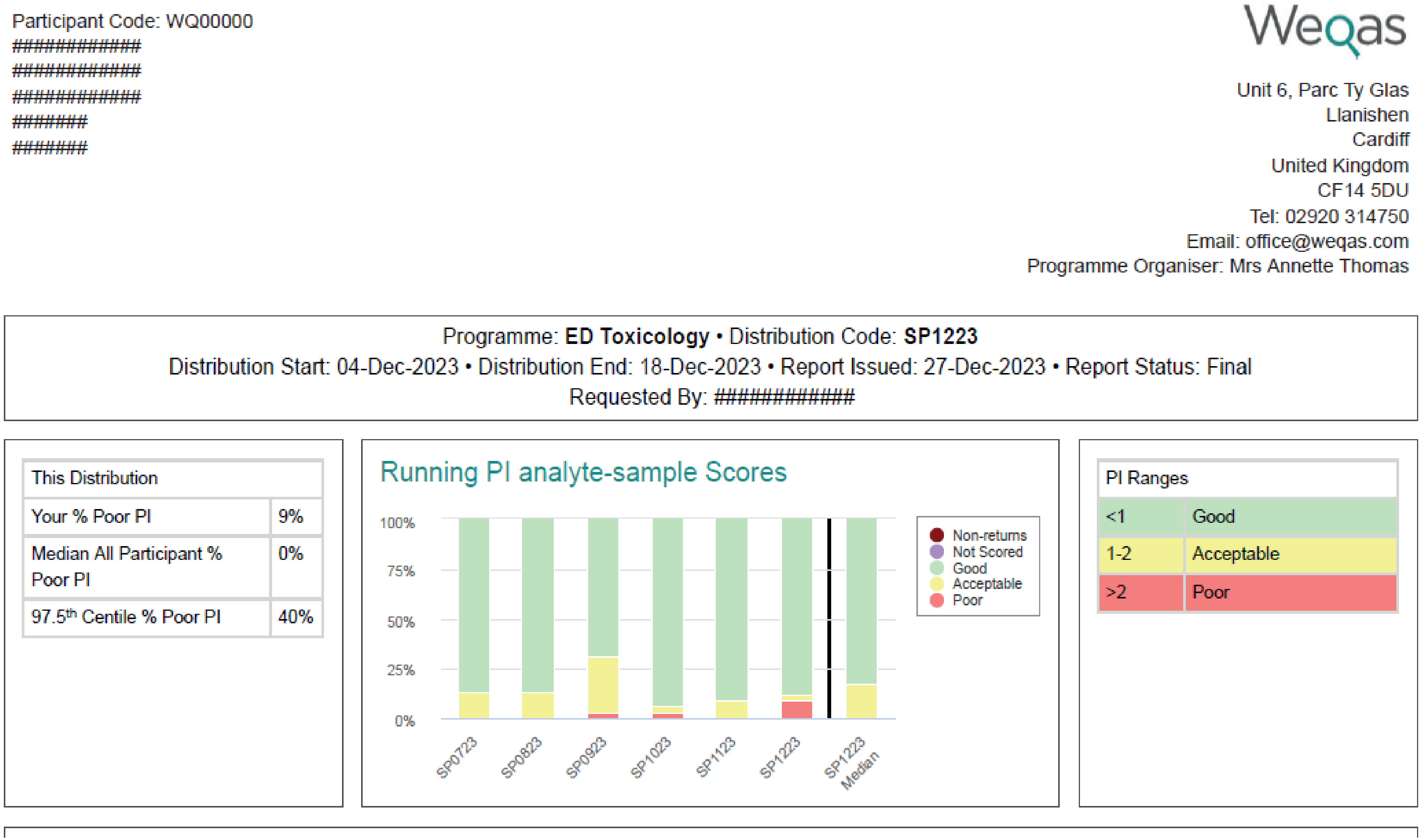
***** **Please note**********

The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by NRR in your PI table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic service.

Distribution Specific Comment

There is no specific comment for this distribution.

No participant comments have been submitted for any instruments for this distribution.



Participant Code: WQ00000
############
############
############
#######
#######

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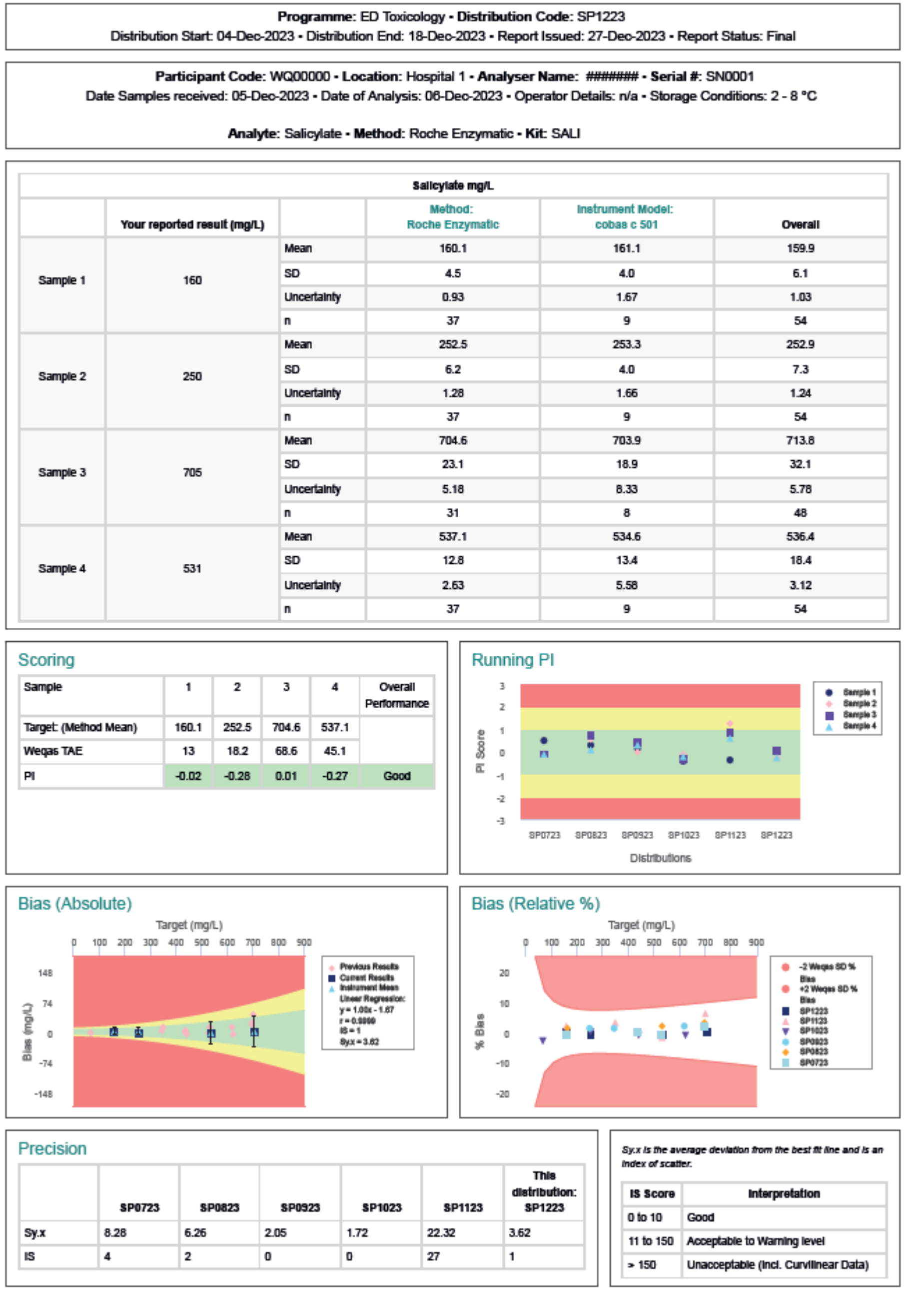


Programme: ED Toxicology • **Distribution Code:** SP1223
Distribution Start: 04-Dec-2023 • Distribution End: 18-Dec-2023 • Report Issued: 27-Dec-2023 • Report Status: Final

Participant Code: WQ00000 • **Location:** Hospital 1 • **Analyser Name:** ####### • **Serial #:** SN0001
Date Samples received: 05-Dec-2023 • Date of Analysis: 06-Dec-2023 • Operator Details: n/a • Storage Conditions: 2 - 8 °C

Analyte: Salicylate • **Method:** Roche Enzymatic • **Kit:** SALI

Salicylate mg/L

	Your reported result (mg/L)		Method: Roche Enzymatic	Instrument Model: cobas c 501	Overall
Sample 1	160	Mean	160.1	161.1	159.9
		SD	4.5	4.0	6.1
		Uncertainty	0.93	1.67	1.03
		n	37	9	54
Sample 2	250	Mean	252.5	253.3	252.9
		SD	6.2	4.0	7.3
		Uncertainty	1.28	1.66	1.24
		n	37	9	54
Sample 3	705	Mean	704.6	703.9	713.8
		SD	23.1	18.9	32.1
		Uncertainty	5.18	8.33	5.78
		n	31	8	48
Sample 4	531	Mean	537.1	534.6	536.4
		SD	12.8	13.4	18.4
		Uncertainty	2.63	5.58	3.12
		n	37	9	54

Scoring

Sample	1	2	3	4	Overall Performance
Target: (Method Mean)	160.1	252.5	704.6	537.1	
Weqas TAE	13	18.2	68.6	45.1	
PI	-0.02	-0.28	0.01	-0.27	Good

Running PI

Bias (Absolute)

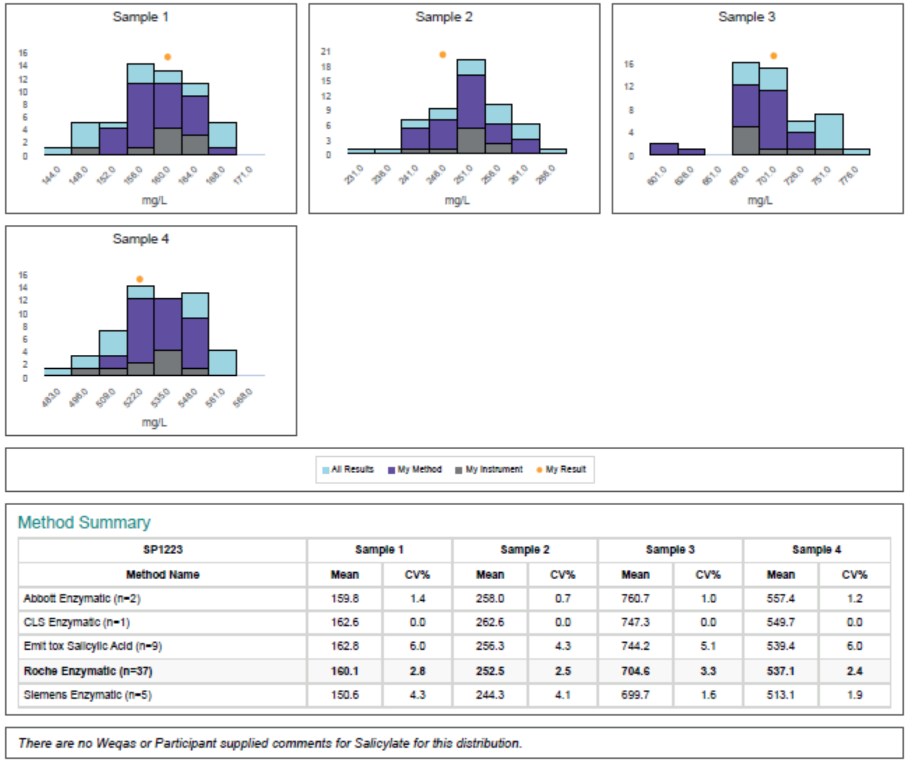
Bias (Relative %)

Precision

	SP0723	SP0823	SP0923	SP1023	SP1123	This distribution: SP1223
Sy.x	8.28	6.26	2.05	1.72	22.32	3.62
IS	4	2	0	0	27	1

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

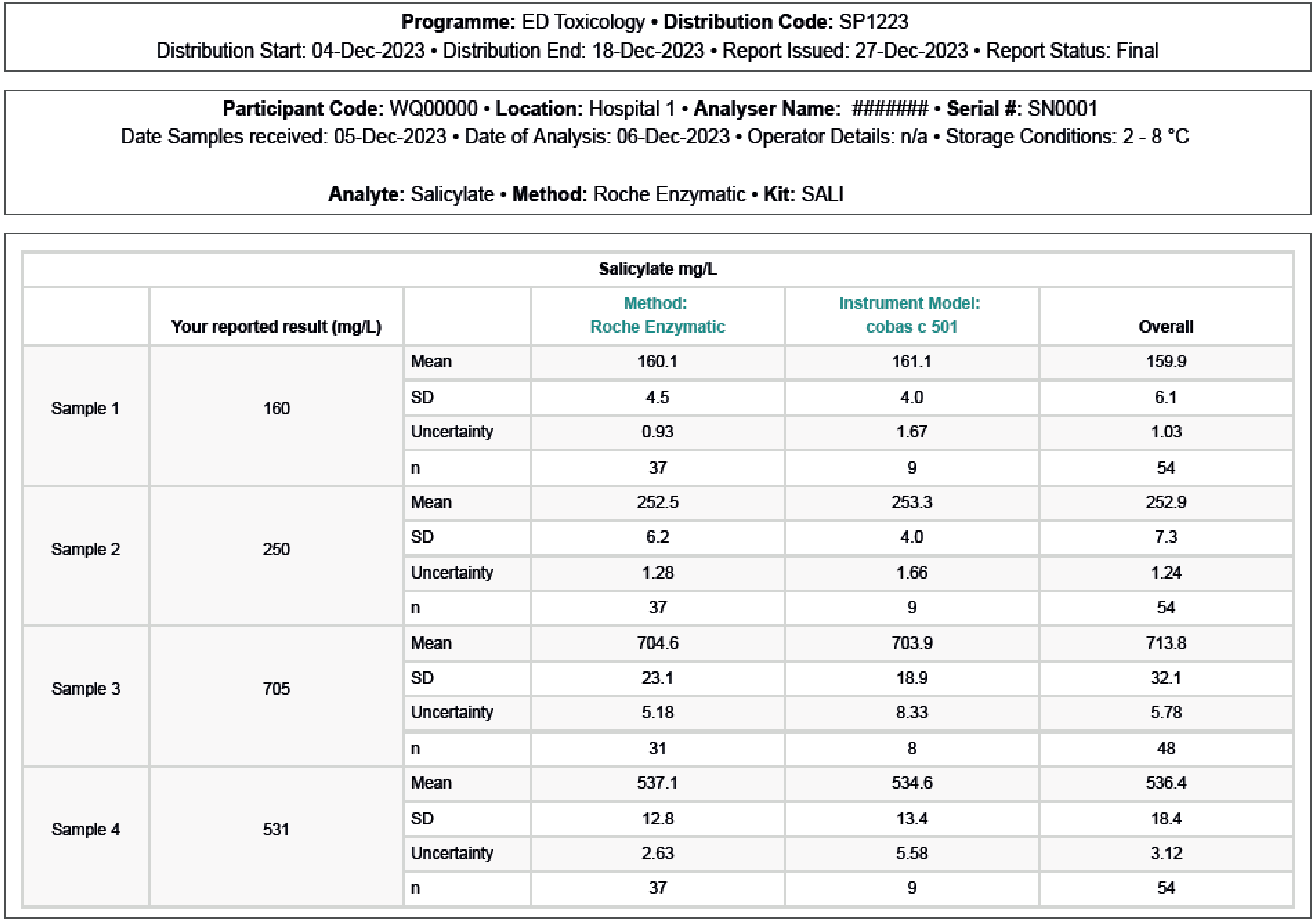
IS Score	Interpretation
0 to 10	Good
11 to 150	Acceptable to Warning level
> 150	Unacceptable (incl. Curvilinear Data)



Method Summary

SP1223	Sample 1		Sample 2		Sample 3		Sample 4	
Method Name	Mean	CV%	Mean	CV%	Mean	CV%	Mean	CV%
Abbott Enzymatic (n=2)	159.8	1.4	258.0	0.7	760.7	1.0	557.4	1.2
CLS Enzymatic (n=1)	162.6	0.0	262.6	0.0	747.3	0.0	549.7	0.0
Emit tox Salicylic Acid (n=9)	162.8	6.0	256.3	4.3	744.2	5.1	539.4	6.0
Roche Enzymatic (n=37)	**160.1**	**2.8**	**252.5**	**2.5**	**704.6**	**3.3**	**537.1**	**2.4**
Siemens Enzymatic (n=5)	150.6	4.3	244.3	4.1	699.7	1.6	513.1	1.9

There are no Weqas or Participant supplied comments for Salicylate for this distribution.



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Salicylate mg/L

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Target: (Method Mean)	160.1	252.5	704.6	537.1	
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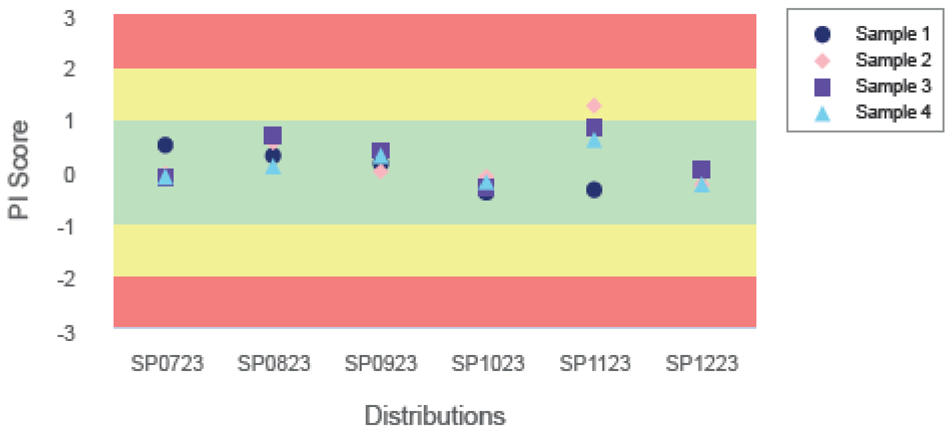
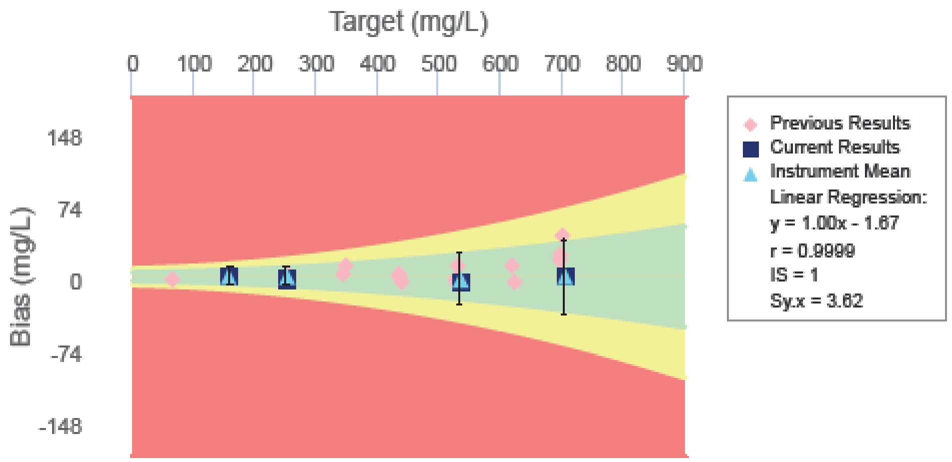
PI	-0.02	-0.28	0.01	-0.27	Good

Running PI

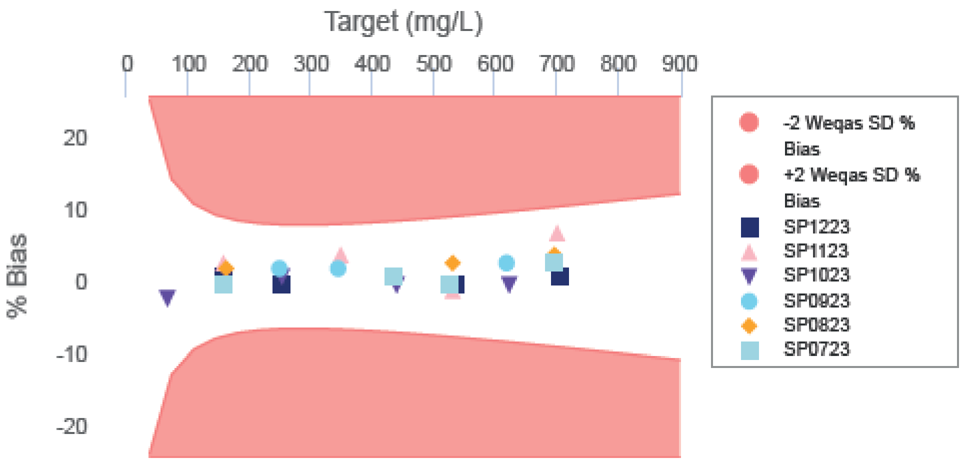


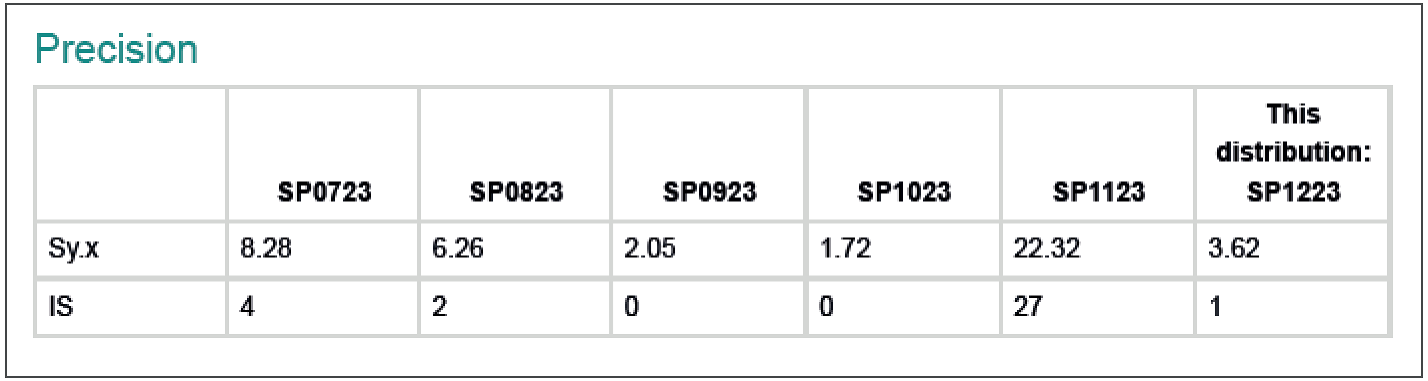
Bias (Absolute)



Linear Regression:
y = 1.00x - 1.67
r = 0.9999
IS = 1
Sy.x = 3.62

Bias (Relative %)





Precision

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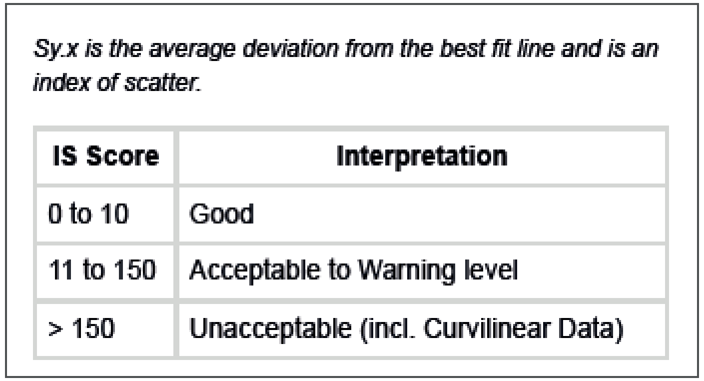

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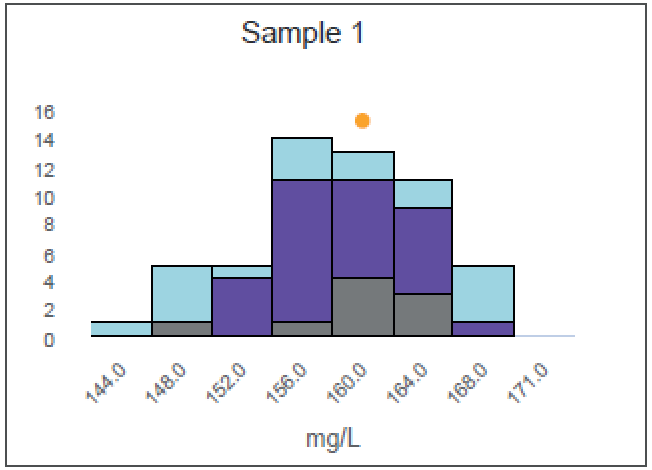
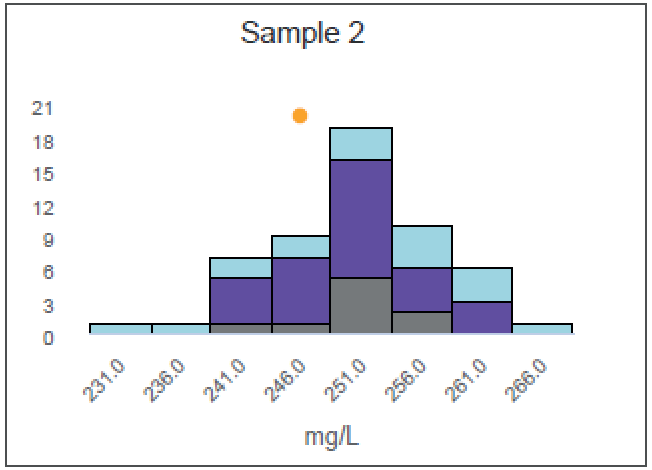
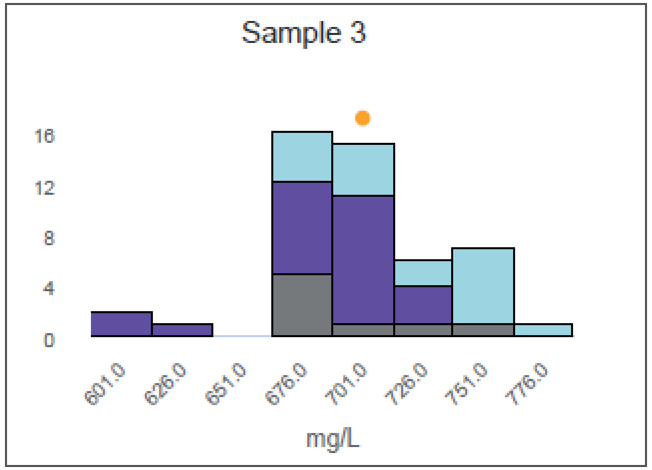
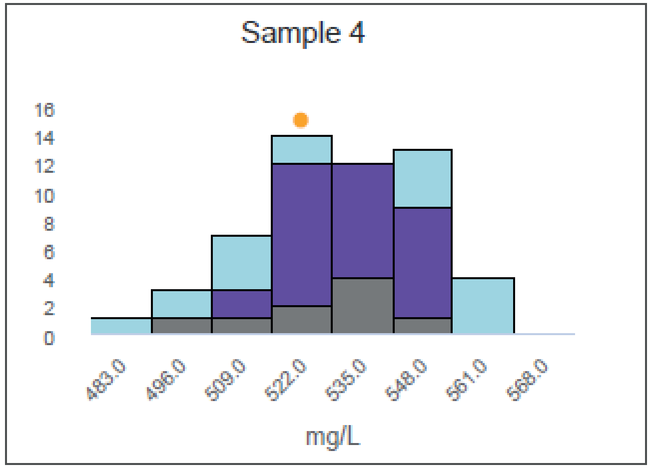
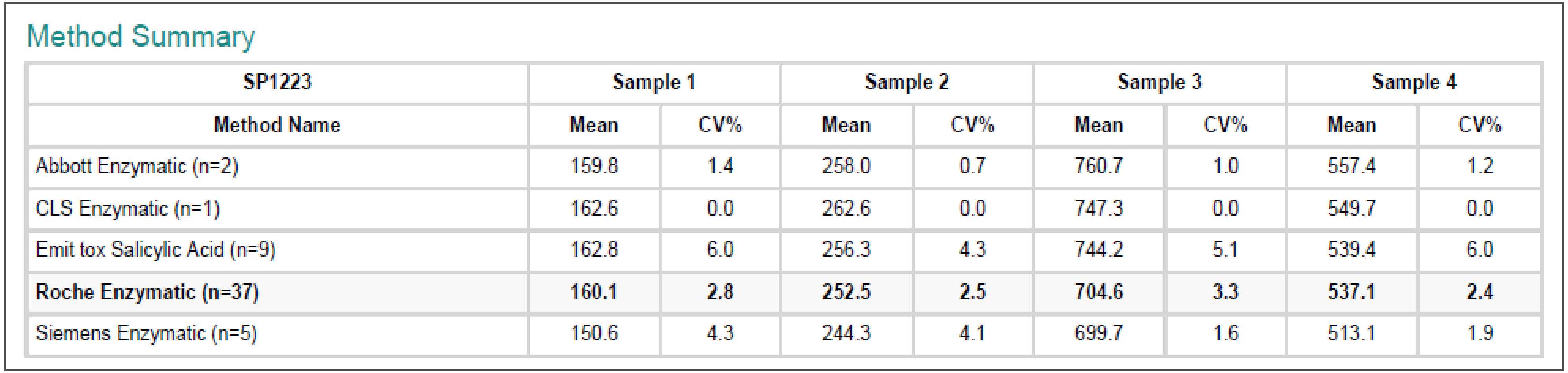

Sample 1


Sample 2


Sample 3


Sample 4



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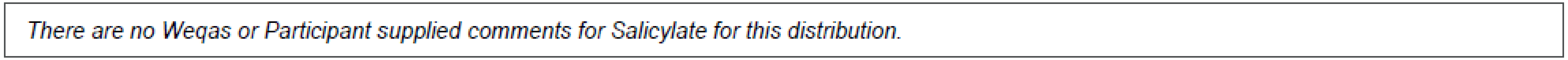
CLS Enzymatic (n=1)	162.6	0.0	262.6	0.0	747.3	0.0	549.7	0.0
Emit tox Salicylic Acid (n=9)	162.8	6.0	256.3	4.3	744.2	5.1	539.4	6.0
Roche Enzymatic (n=37)	**160.1**	**2.8**	**252.5**	**2.5**	**704.6**	**3.3**	**537.1**	**2.4**
Siemens Enzymatic (n=5)	150.6	4.3	244.3	4.1	699.7	1.6	513.1	1.9



There are no Weqas or Participant supplied comments for Salicylate for this distribution.

Overall Performance

Traffic light colour	**Performance category**	**Description**
Red	Non-Return	(Any number of samples in distribution) and (No results submitted for any samples)
	Poor	(Any number of sample in distribution) and (one or more |PI| > 3)
		(number of samples in distribution = 1) and (2<|PI| ≤ 3)
		(number of samples in distribution > 1) and (2 or more |PI| > 2) *(Westgard 2_{2s})*
		(number of samples in distribution > 1) AND (sign x_i ≠ sign x_j)] AND $\lvert x_i \rvert>2$ AND $\lvert x_j \rvert > 2$ * for at least one pair of scores x_i and x_j where x_n with i≠j are the individual sample-analyte scores for the instrument in question *(Westgard R_{4s})*
Orange	Warning	(number of samples in distribution > 1) and (single sample with 2 < |PI| ≤ 3) and (no sample with |PI| > 3)
Yellow	Acceptable	(any number of samples in distribution) AND (1 < Max |PI| ≤ 2)
Green	Good	|PI| < 1 for all samples Green is only assigned if all the individual samples are good.

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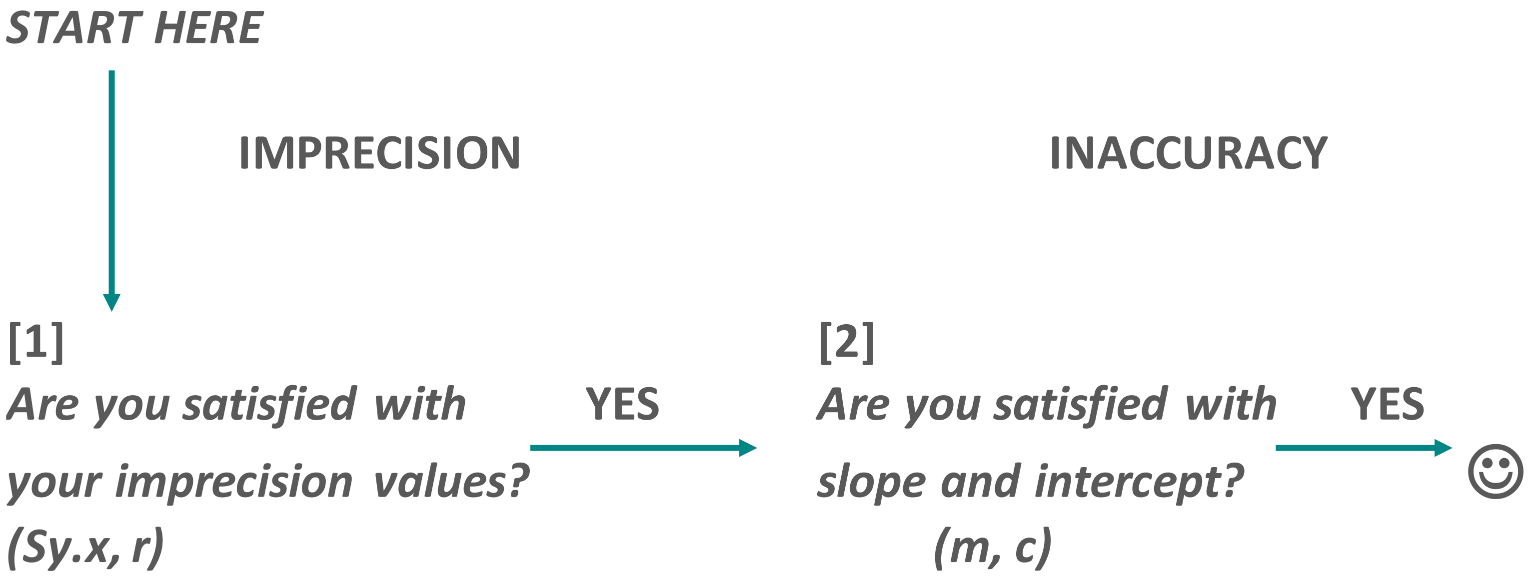
Problem Solving and Cases

Problem Solving Flow Chart



START HERE

IMPRECISION

INACCURACY

[1]

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

YES

[2]

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

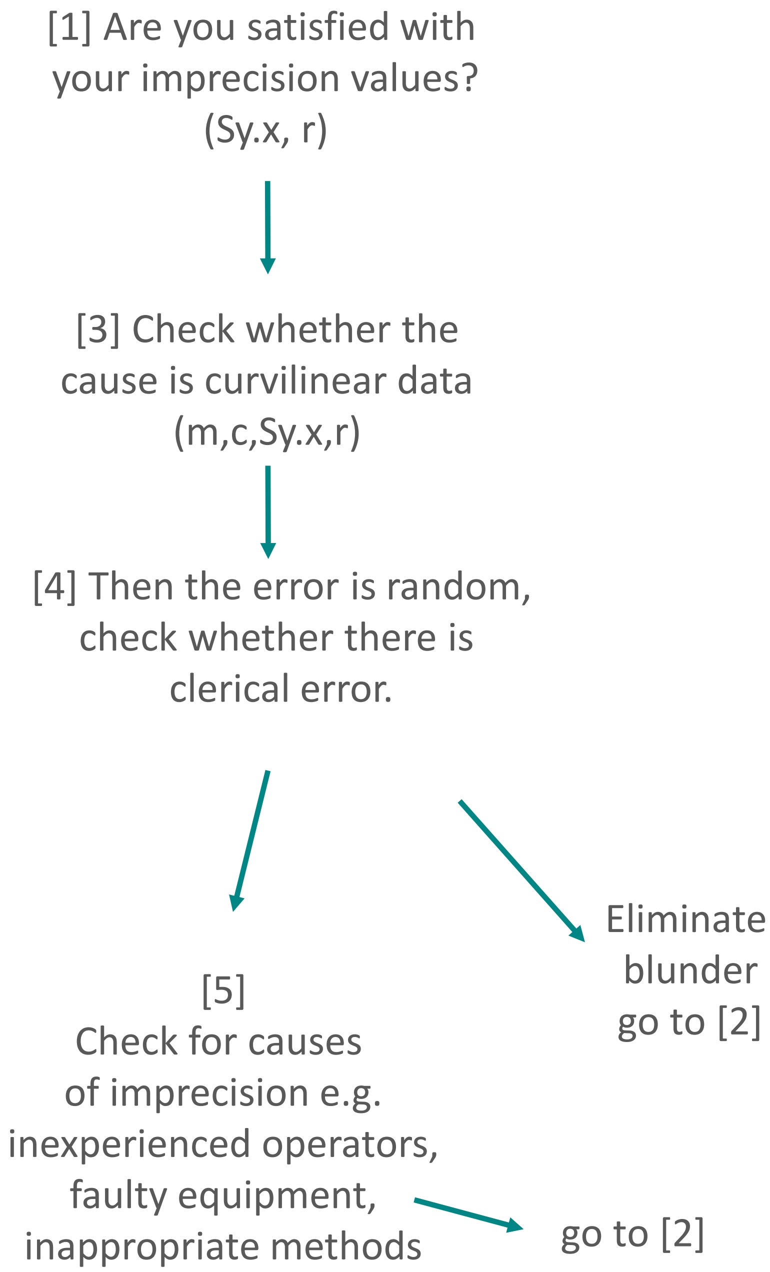
YES

☺

Pages 18-19 of SP-QL1-IntLabEQA

Problem Solving Flow Chart

IMPRECISION



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

[3] Check whether the cause is curvilinear data (m,c,Sy.x,r)

[4] Then the error is random, check whether there is clerical error.

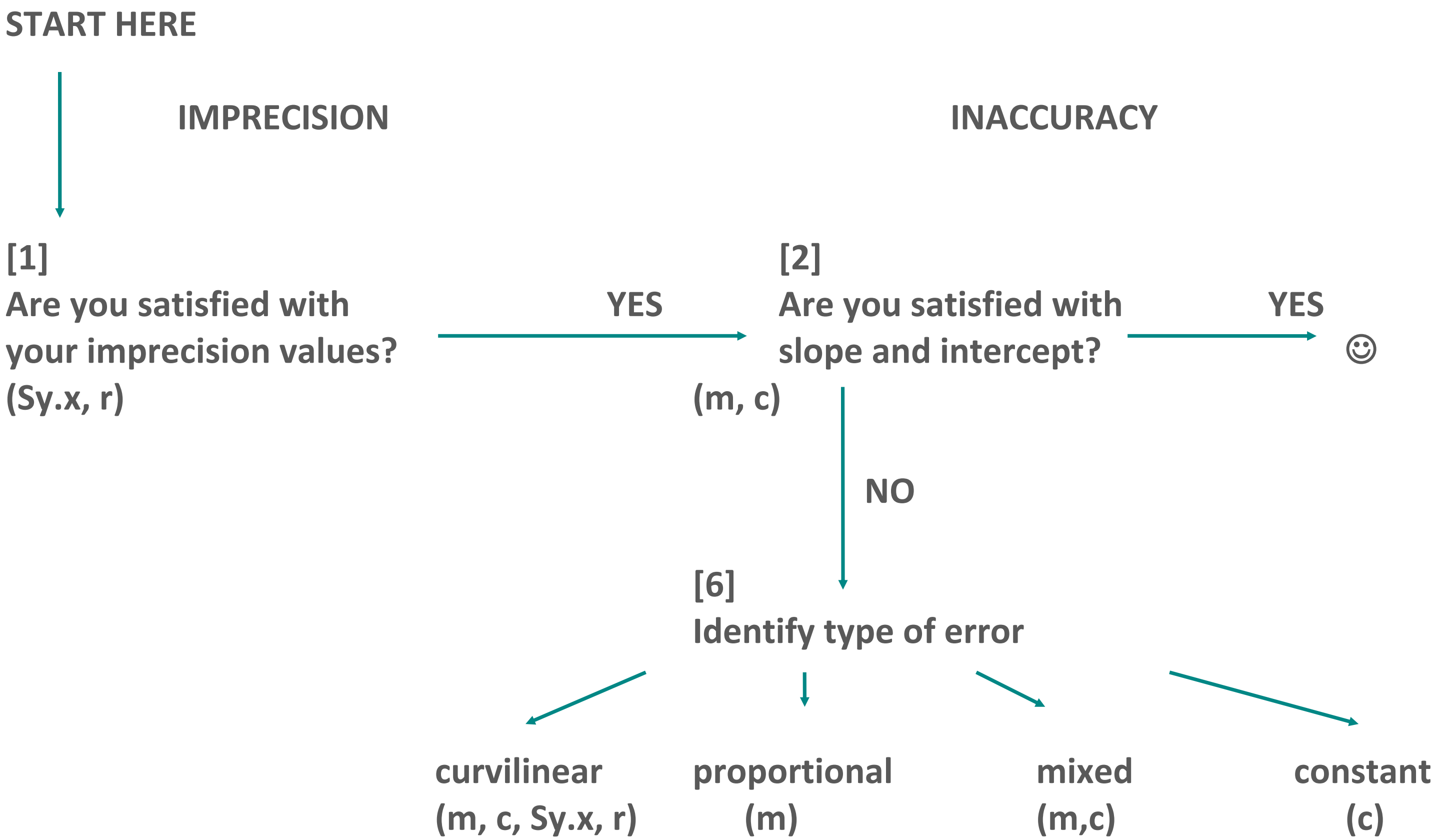
Eliminate blunder go to [2]

[5]
Check for causes of imprecision e.g. inexperienced operators, faulty equipment, inappropriate methods

go to [2]

Pages 18-19 of SP-QL1-IntLabEQA

Problem Solving Flow Chart



START HERE

IMPRECISION

INACCURACY

[1]
Are you satisfied with
your imprecision values?
(Sy.x, r)

YES

[2]
Are you satisfied with
slope and intercept?
(m, c)

YES

☺

NO

[6]
Identify type of error

curvilinear
(m, c, Sy.x, r)

proportional
(m)

mixed
(m,c)

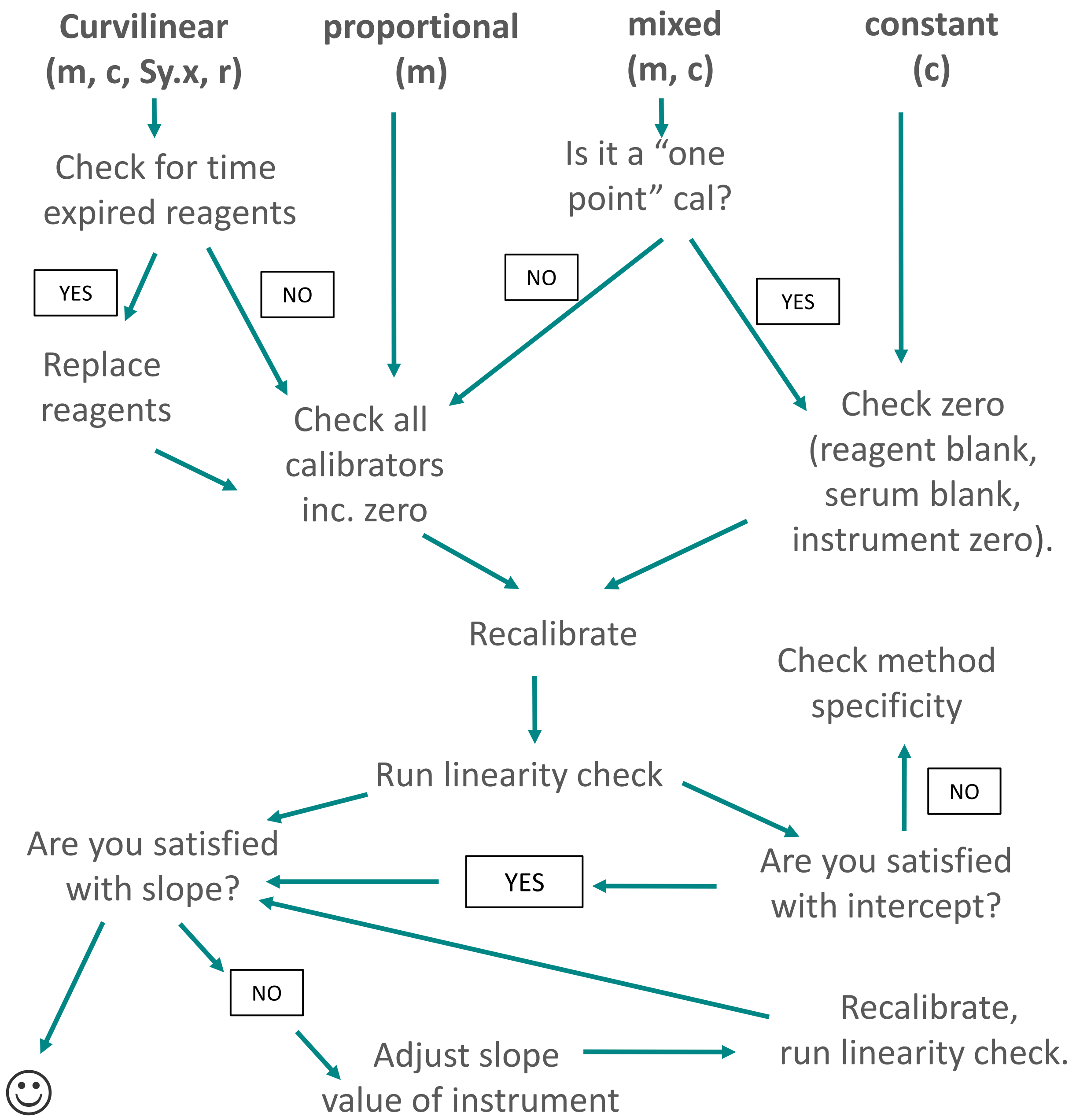
constant
(c)

Pages 18-19 of SP-QL1-IntLabEQA

Weqas

Problem Solving Flow Chart

INACCURACY



Curvilinear (m, c, Sy.x, r)

Check for time expired reagents

YES

Replace reagents

NO

proportional (m)

Check all calibrators inc. zero

mixed (m, c)

Is it a “one point” cal?

NO

YES

constant (c)

Check zero (reagent blank, serum blank, instrument zero).

Recalibrate

Run linearity check

Are you satisfied with intercept?

NO

Check method specificity

YES

Are you satisfied with slope?

☺

NO

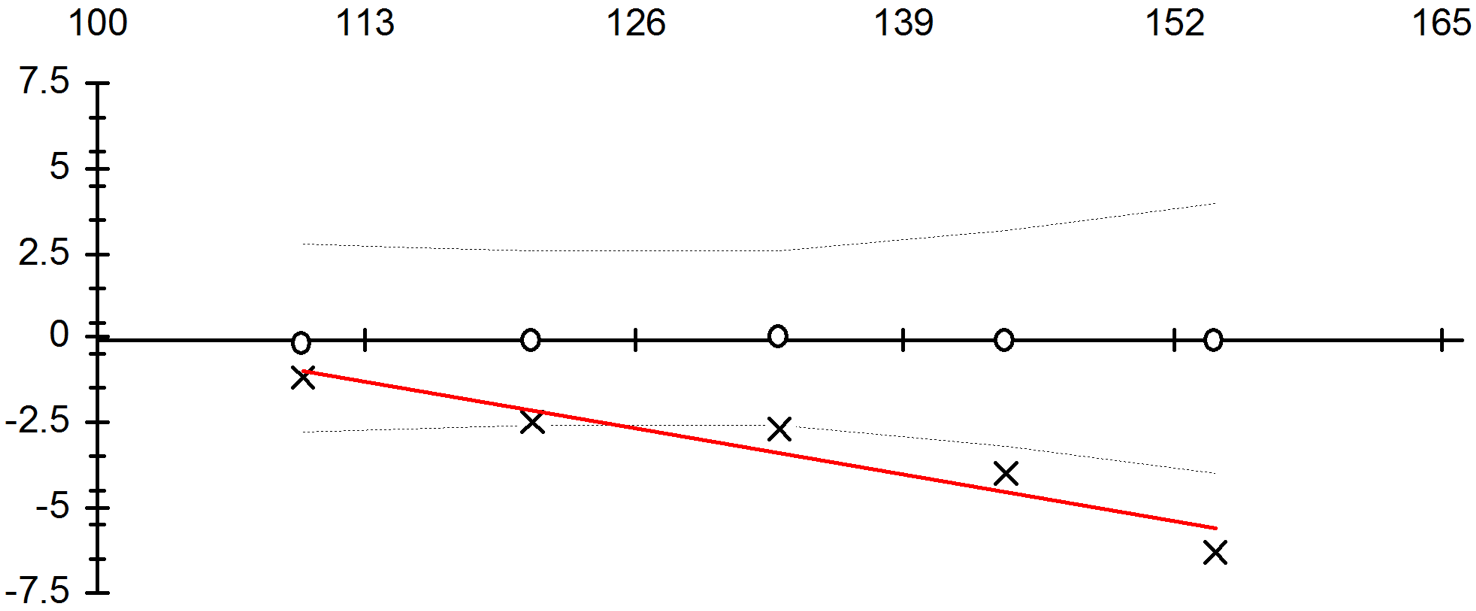
Adjust slope value of instrument

Recalibrate, run linearity check.

Pages 18-19 of SP-QL1-IntLabEQA

Bias plot (1)

Sodium (mmol/l)



y = 0.9x + 9.6

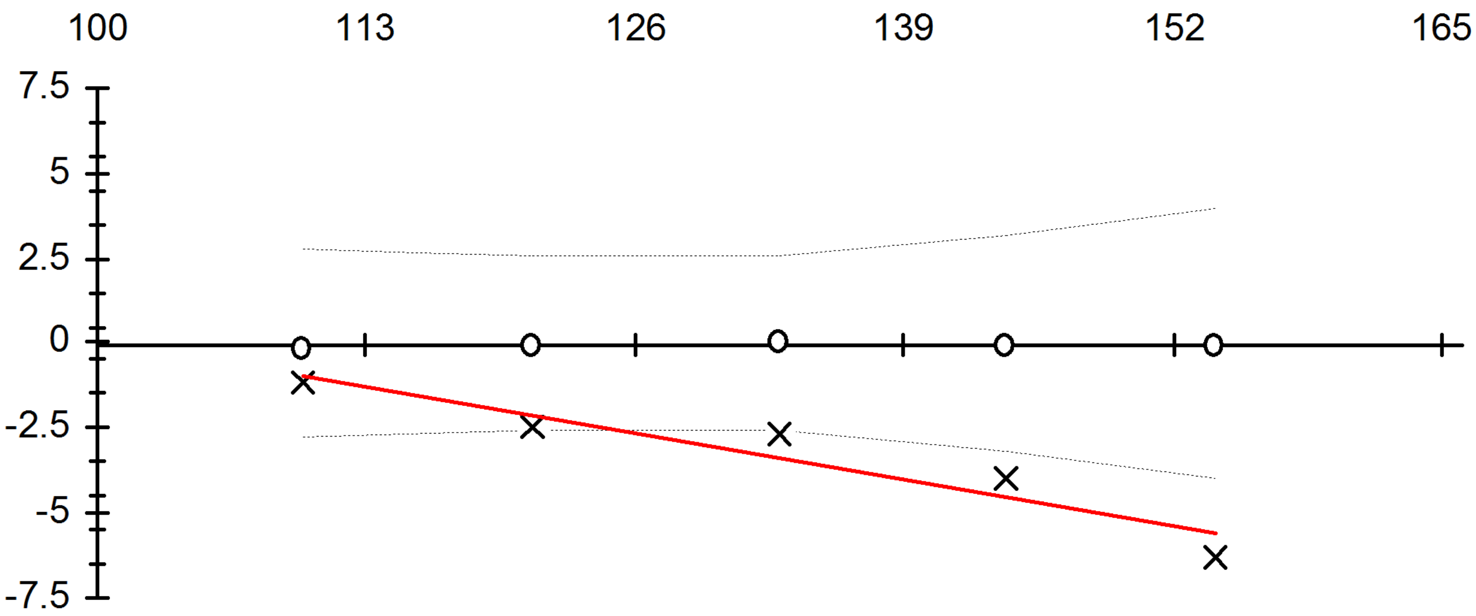
r = 0.9995

IS = 5

Sy.x = 0.63

Bias plot (1)

Sodium (mmol/l)



y = 0.9x + 9.6

r = 0.9995

IS = 5

Sy.x = 0.63

Imprecision – satisfactory

Inaccuracy – identify error

m= 0.9, c = +9.6 mmol/L – OK at 100 mmol/L

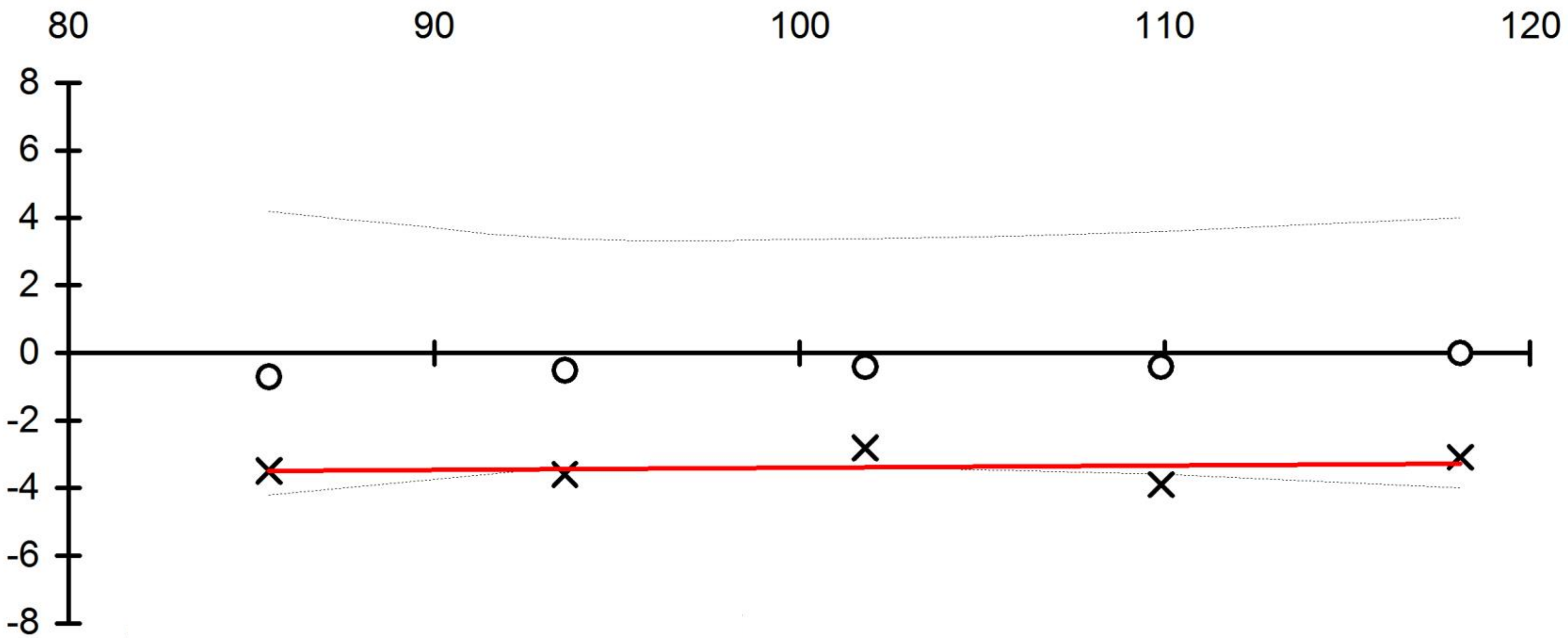
2.5% negative bias at 130 mmol/L, 4% negative bias at 160 mmol/L

Error – mixed. Two points calibration at 110 and 160 mmol/L

Cause – incorrect values for 160 mmol/L calibration

Bias plot (2)

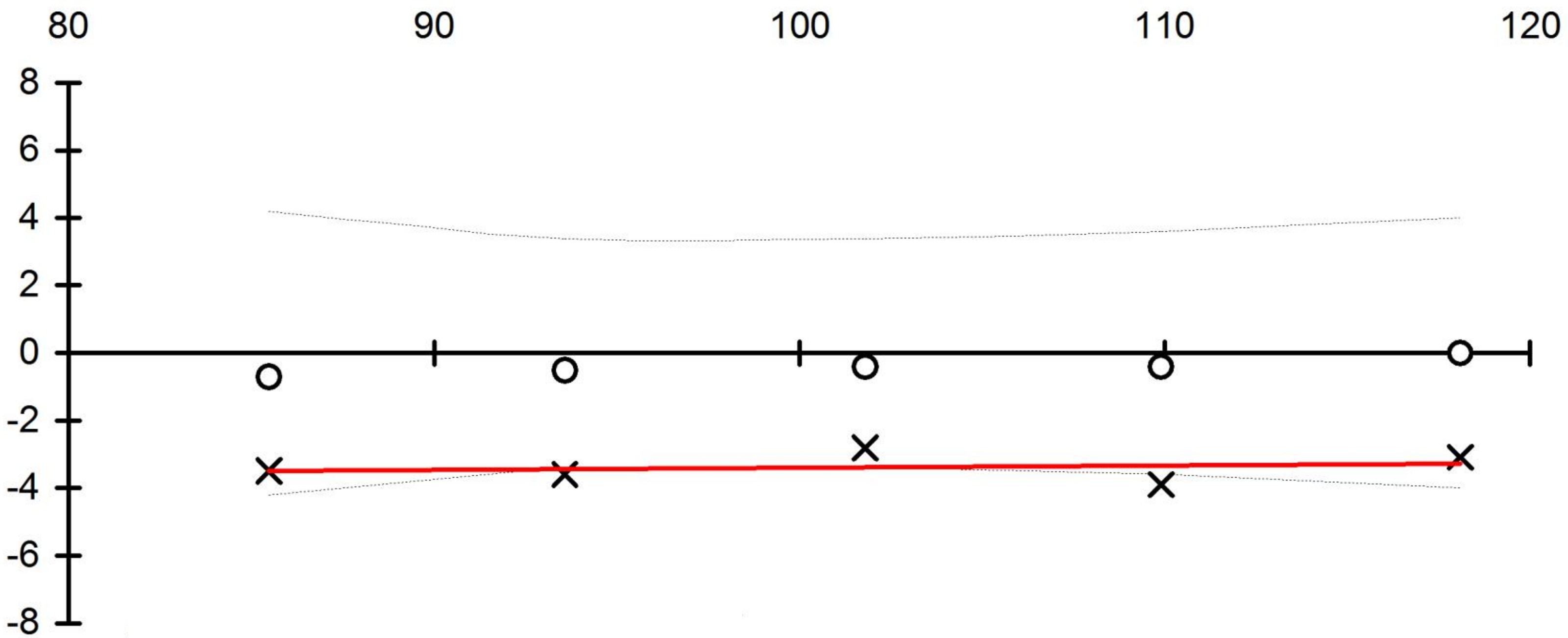
Chloride (mmol/l)



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

Bias plot (2)

Chloride (mmol/l)

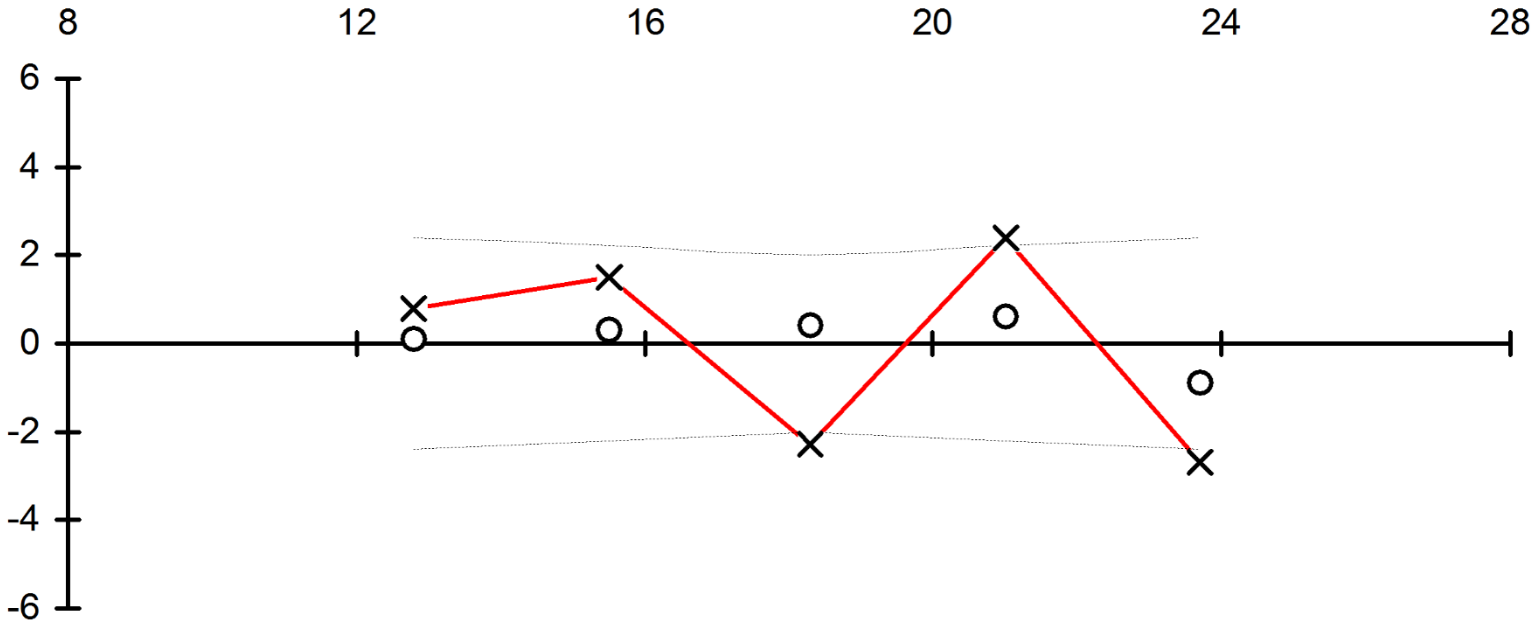


y = 1.01x -4.01
r = 0.9995
IS = 5
Sy.x = 0.49

Imprecision – satisfactory
Inaccuracy – identify error
c = -4.0 mmol/L
Error – systematic absolute. Results low by 4.0 mmol/L over whole range
Cause – incorrect serum blank compensation

Bias plot (3)

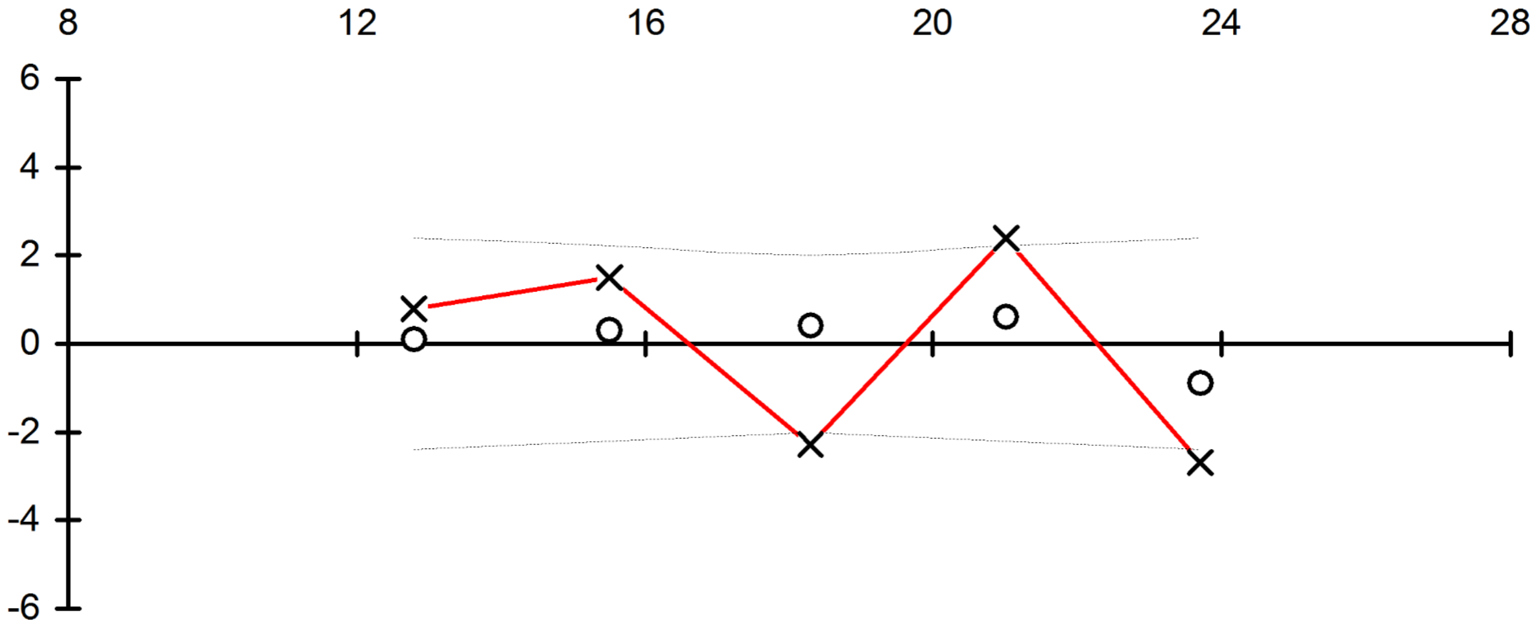
Bicarbonate (mmol/l)



y = slope not calculated
r = 0.8484
IS = 1516
Sy.x = 2.41

Bias plot (3)

Bicarbonate (mmol/l)

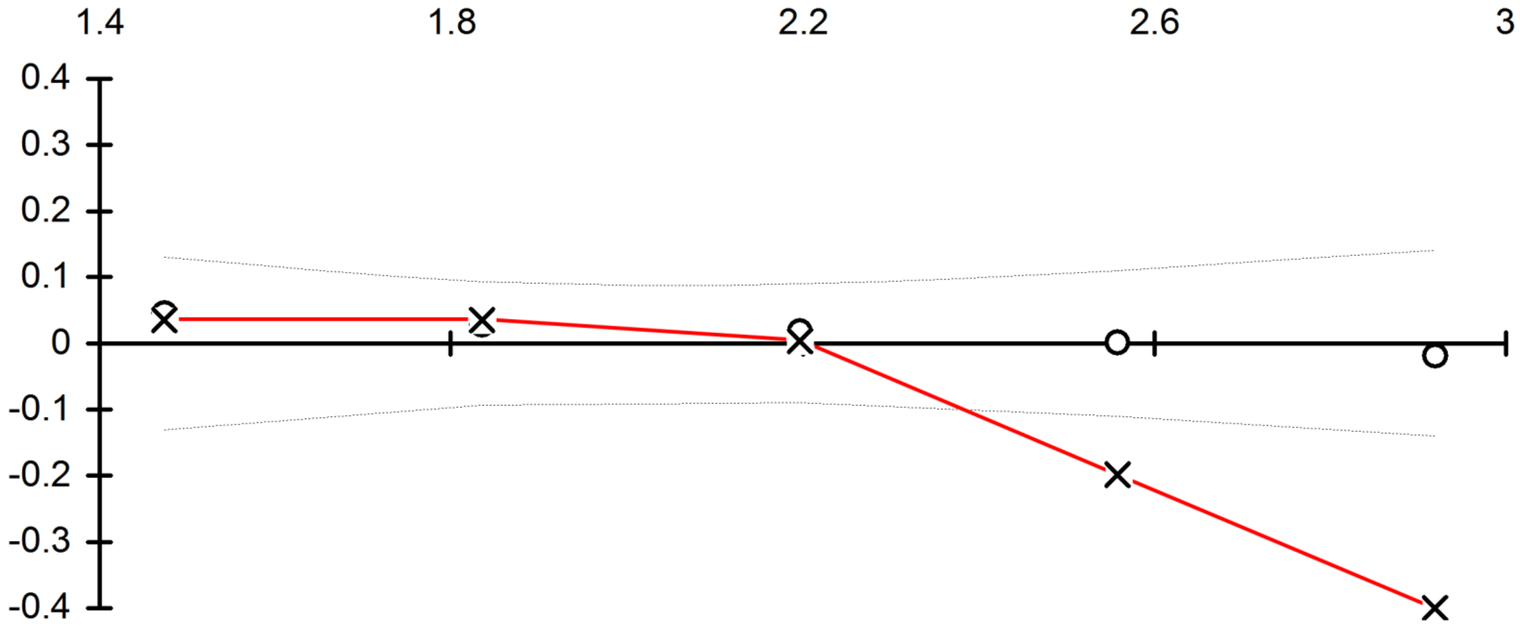


y = slope not calculated
r = 0.8484
IS = 1516
Sy.x = 2.41

Imprecision – unsatisfactory, r = 0.8484, Sy.x = 2.4 mmol/L
Not curvilinear
Error – random
Cause – faulty syringe on instrument

Bias plot (4)

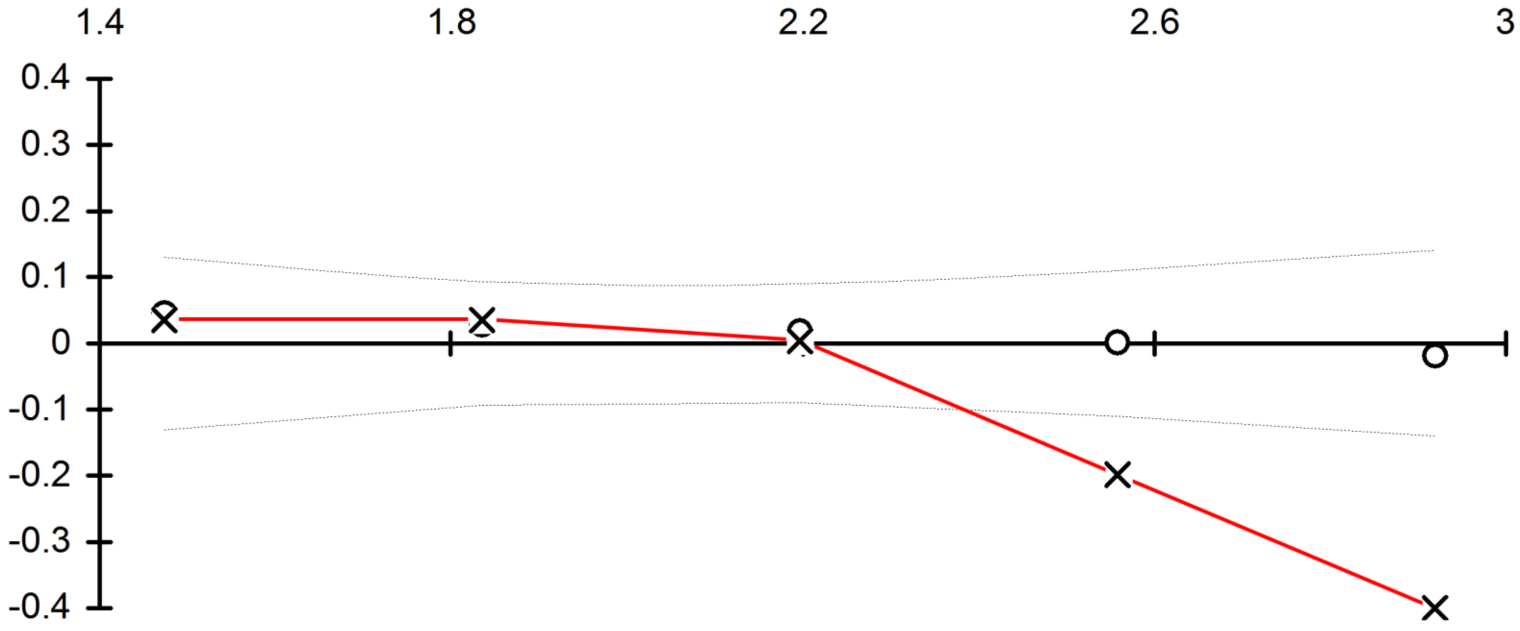
Calcium (mmol/l)



y = slope not calculated
r = 0.9810
IS = 190
Sy.x = 0.09

Bias plot (4)

Calcium (mmol/l)

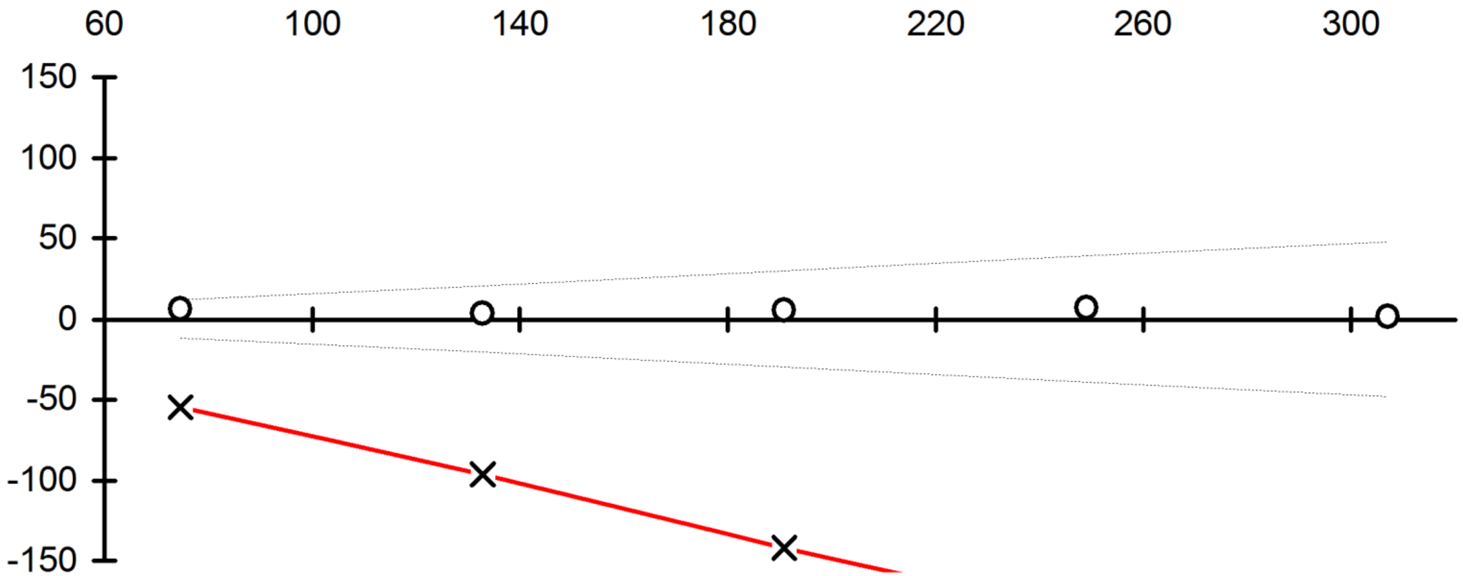


y = slope not calculated
r = 0.9810
IS = 190
Sy.x = 0.09

Imprecision – unsatisfactory, r = 0.9810, Sy.x = 0.09 mmol/L
Error – curvilinear data
Cause – time expired reagents

Bias plot (5)

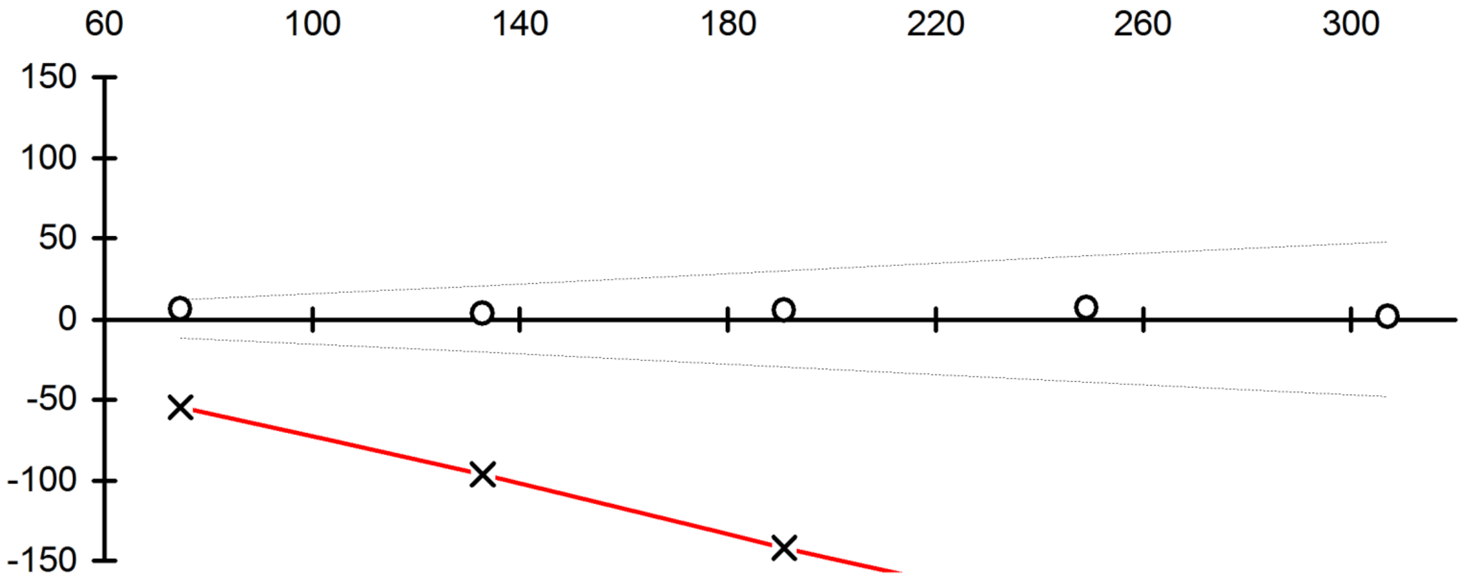
ALP (IU/L)



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

Bias plot (5)

ALP (IU/L)



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

Imprecision – satisfactory
Inaccuracy – identify error
m = 0.57
Error – systematic proportional error. Results low by 41% over the whole range
Cause – incorrect method group classification. The lab was using AMP not DEA buffer

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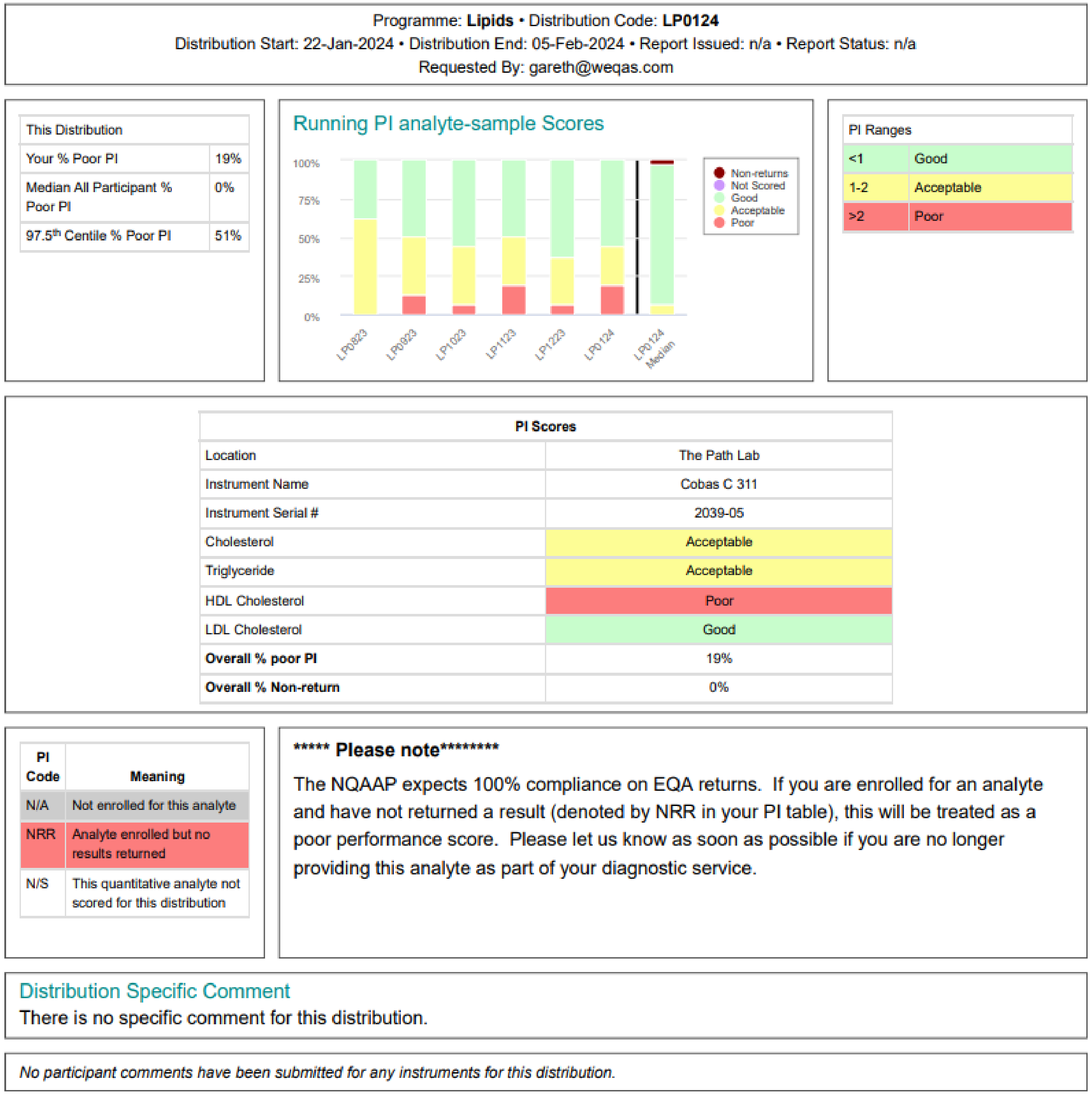
Case Study - example

Summary Report

Analyte:
Overall Performance Category:
Running PI analyte –sample scores:

Standard Report

Analyte results table:
Scoring Table:
Running PI scores:
Bias Chart (Absolute):
Bias Chart (Relative):
Precision Scores:
Sample Histograms:
Method Summary Data:



Programme: **Lipids** • Distribution Code: **LP0124**
Distribution Start: 22-Jan-2024 • Distribution End: 05-Feb-2024 • Report Issued: n/a • Report Status: n/a
Requested By: gareth@weqas.com

This Distribution	
Your % Poor PI	19%
Median All Participant % Poor PI	0%
97.5th Centile % Poor PI	51%

Running PI analyte-sample Scores

PI Ranges	
<1	Good
1-2	Acceptable
>2	Poor

PI Scores	
Location	The Path Lab
Instrument Name	Cobas C 311
Instrument Serial #	2039-05
Cholesterol	Acceptable
Triglyceride	Acceptable
HDL Cholesterol	Poor
LDL Cholesterol	Good
Overall % poor PI	19%
Overall % Non-return	0%

PI Code	**Meaning**
N/A	Not enrolled for this analyte
NRR	Analyte enrolled but no results returned
N/S	This quantitative analyte not scored for this distribution

******* Please note**********

The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by NRR in your PI table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic service.

Distribution Specific Comment

There is no specific comment for this distribution.

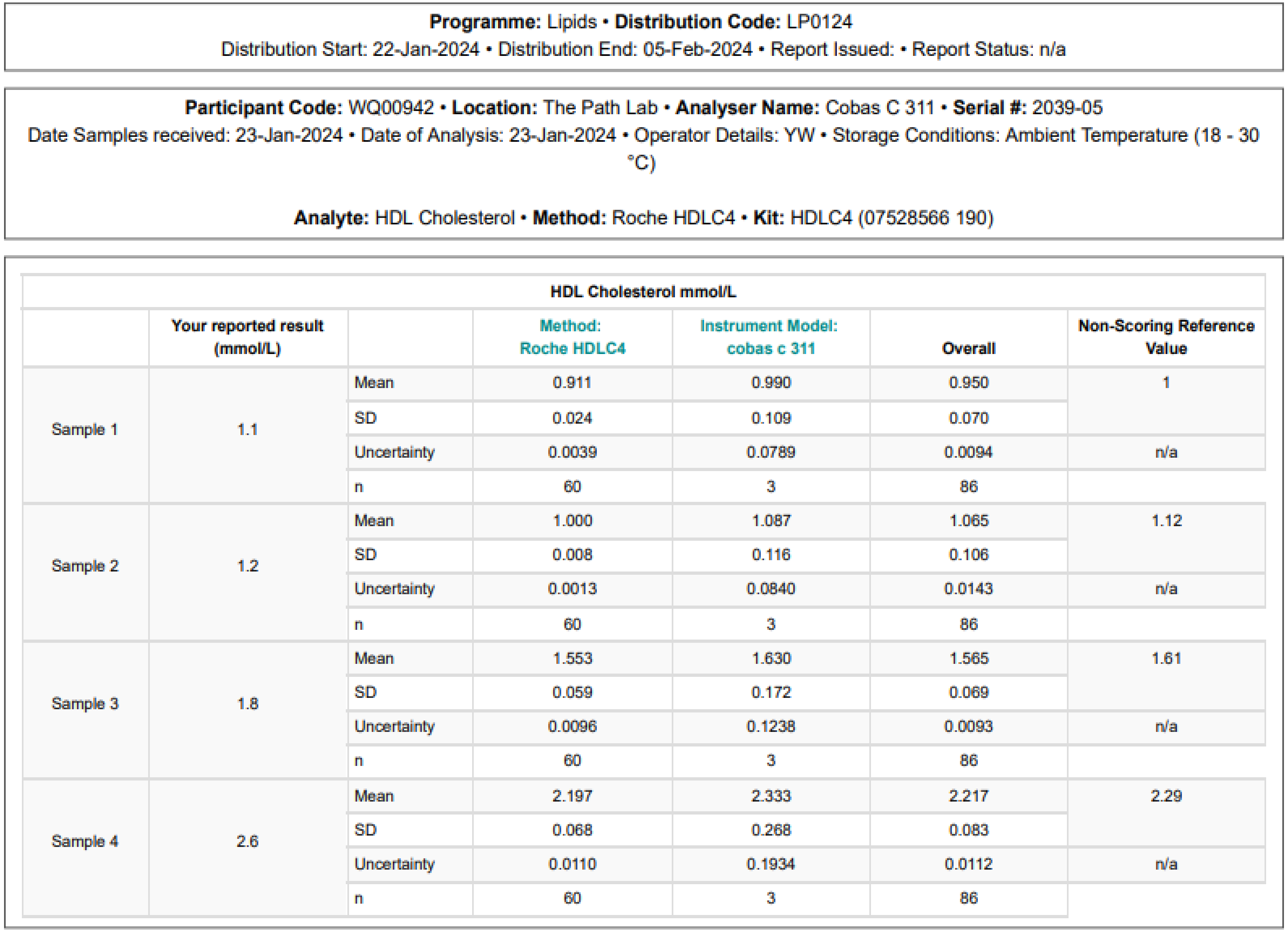
No participant comments have been submitted for any instruments for this distribution.

Summary Report

Analyte: HDL

Overall Performance Category: Poor

Running PI analyte –sample scores: >50% good, some acceptable some poor. More poor and less good than median



Programme: Lipids • **Distribution Code:** LP0124
Distribution Start: 22-Jan-2024 • Distribution End: 05-Feb-2024 • Report Issued: • Report Status: n/a

Participant Code: WQ00942 • **Location:** The Path Lab • **Analyser Name:** Cobas C 311 • **Serial #:** 2039-05
Date Samples received: 23-Jan-2024 • Date of Analysis: 23-Jan-2024 • Operator Details: YW • Storage Conditions: Ambient Temperature (18 - 30 °C)

Analyte: HDL Cholesterol • **Method:** Roche HDLC4 • **Kit:** HDLC4 (07528566 190)

HDL Cholesterol mmol/L						
	Your reported result (mmol/L)		**Method: Roche HDLC4**	**Instrument Model: cobas c 311**	**Overall**	**Non-Scoring Reference Value**
Sample 1	1.1	Mean	0.911	0.990	0.950	1
		SD	0.024	0.109	0.070	
		Uncertainty	0.0039	0.0789	0.0094	n/a
		n	60	3	86	
Sample 2	1.2	Mean	1.000	1.087	1.065	1.12
		SD	0.008	0.116	0.106	
		Uncertainty	0.0013	0.0840	0.0143	n/a
		n	60	3	86	
Sample 3	1.8	Mean	1.553	1.630	1.565	1.61
		SD	0.059	0.172	0.069	
		Uncertainty	0.0096	0.1238	0.0093	n/a
		n	60	3	86	
Sample 4	2.6	Mean	2.197	2.333	2.217	2.29
		SD	0.068	0.268	0.083	
		Uncertainty	0.0110	0.1934	0.0112	n/a
		n	60	3	86	

Summary Report

Analyte: HDL
Overall Performance Category: Poor
Running PI analyte –sample scores: >50% good, some acceptable some poor. More poor and less good than median

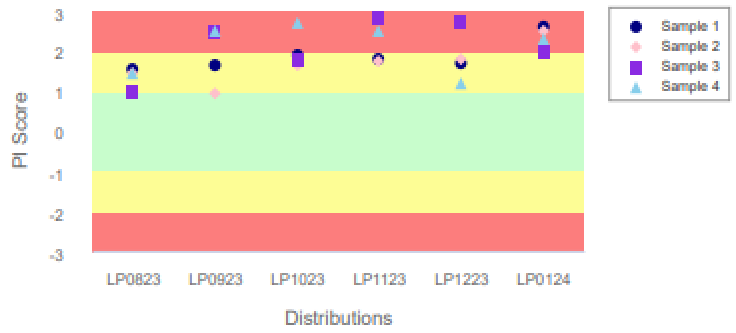
Standard Report

Analyte results table: your results higher than method mean, higher than instrument mean but n only 3. Non scoring ref value

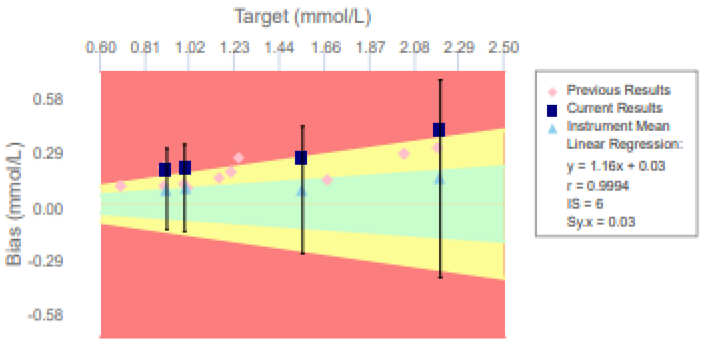
Scoring

Sample	1	2	3	4	Overall Performance
Target: (Method Mean)	0.911	1	1.553	2.197	
Weqas TAE	0.146	0.16	0.248	0.352	
PI	2.6	2.5	1.99	2.29	Poor

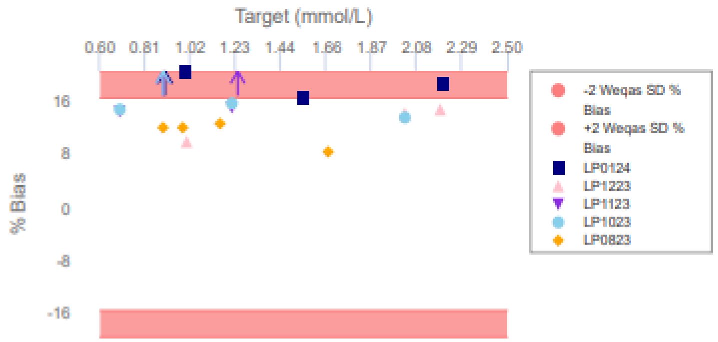
Running PI



Bias (Absolute)



Bias (Relative %)



Precision

	LP0823	LP0923	LP1023	LP1123	LP1223	This distribution: LP0124
Sy.x	0.02	0.05	0.04	0.05	0.06	0.03
IS	7	11	12	80	20	6

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

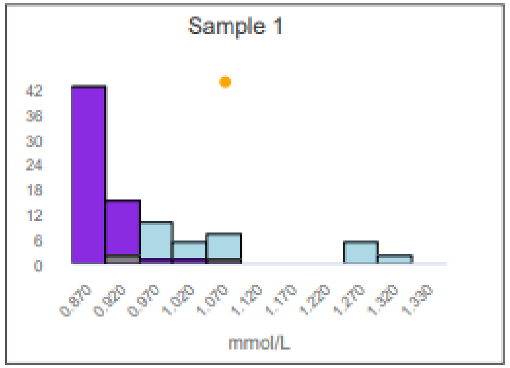
IS Score	Interpretation
0 to 10	Good
11 to 150	Acceptable to Warning level
> 150	Unacceptable (incl. Curvilinear Data)

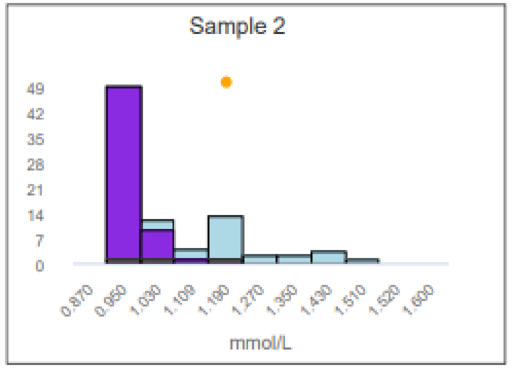
Summary Report

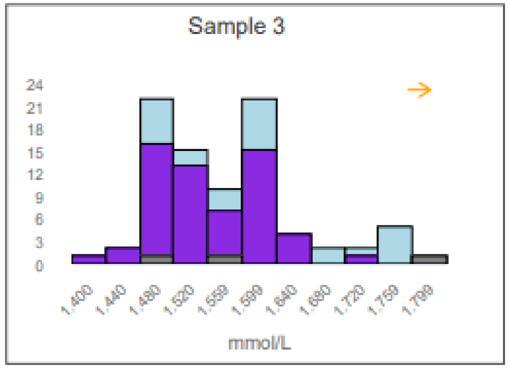
Analyte: HDL
Overall Performance Category: Poor
Running PI analyte –sample scores: >50% good, some acceptable some poor. More poor and less good than median

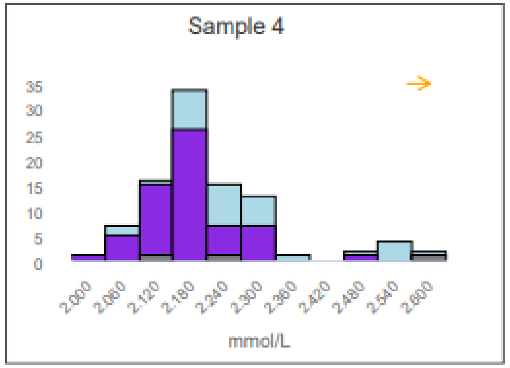
Standard Report

Analyte results table: your results higher than method mean, higher than instrument mean but n only 3. Non scoring ref value
Scoring Table: 3 samples poor PI, 1 sample acceptable but PI 1.99.
Running PI scores: LP0823 acceptable, since them got worse, mostly poor for LP0124
Bias Chart (Absolute): longstanding positive bias, this dist worse than previous, instrument mean close to method mean, y = 1.16*x + 0.03, 16% positive proportional bias. Instrument SDs wide but n = 3
Bias Chart (Relative): longstanding positive bias
Precision Scores: precision good, previously good or acceptable









▨ All Results ■ My Method ■ My Instrument ● My Result

Method Summary

LP0124	Sample 1		Sample 2		Sample 3		Sample 4	
Method Name	**Mean**	**CV%**	**Mean**	**CV%**	**Mean**	**CV%**	**Mean**	**CV%**
Elimination (n=8)	1.225	13.0	1.381	10.9	1.754	1.5	2.475	7.8
Enzymatic Immunoinhibition (n=14)	1.046	4.8	1.193	4.3	1.564	3.7	2.217	3.4
NMR Spectroscopy (n=1)	1.280	0.0	1.290	0.0	1.590	0.0	2.280	0.0
Roche HDLC4 (n=60)	**0.911**	**2.6**	**1.000**	**0.8**	**1.553**	**3.8**	**2.197**	**3.1**
Vitros (n=3)	1.033	6.3	1.200	0.0	1.633	4.0	2.333	2.8

There are no Weqas or Participant supplied comments for HDL Cholesterol for this distribution.

Summary Report

Analyte: HDL

Overall Performance Category: Poor

Running PI analyte –sample scores: >50% good, some acceptable some poor. More poor and less good than median

Standard Report

Analyte results table: your results higher than method mean, higher than instrument mean but n only 3. Non scoring ref value

Scoring Table: 3 samples poor PI, 1 sample acceptable but PI 1.99.

Running PI scores: LP0823 acceptable, since them got worse, mostly poor for LP0124

Bias Chart (Absolute): longstanding positive bias, this dist worse than previous, instrument mean close to method mean, y = 1.16*x + 0.03, 16% positive proportional bias. Instrument SDs wide but n = 3

Bias Chart (Relative): longstanding positive bias

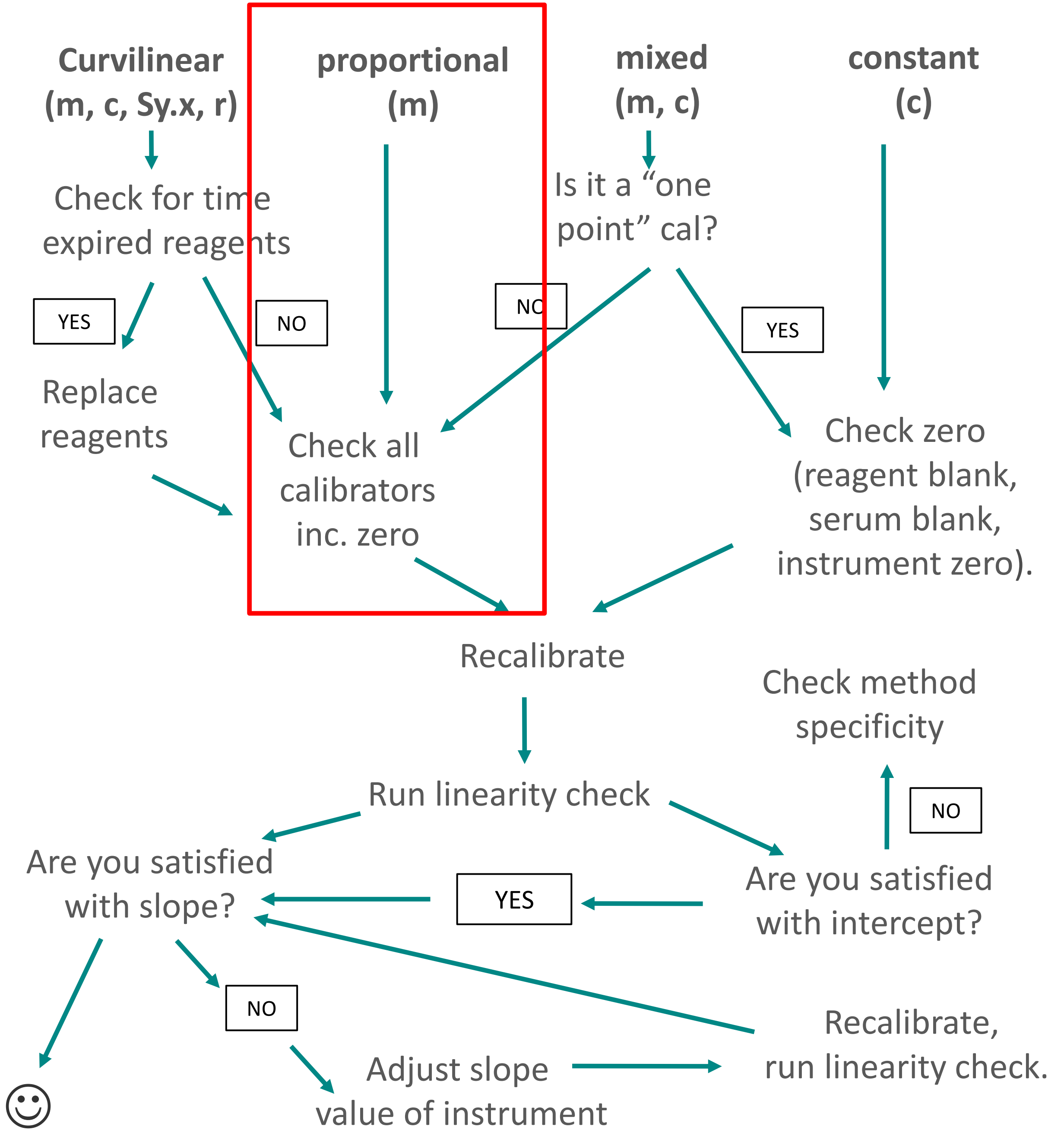
Precision Scores: precision good, previously good or acceptable

Sample Histograms: samples 3 and 4 off the scale, samples 1 and 2 not gaussian distributions but our result to the right of majority

Method Summary Data: Roche method negative bias to other methods

Problem Solving Flow Chart

INACCURACY



Curvilinear (m, c, Sy.x, r)

proportional (m)

mixed (m, c)

constant (c)

Check for time expired reagents

YES

Replace reagents

NO

Is it a "one point" cal?

NO

YES

Check all calibrators inc. zero

Check zero (reagent blank, serum blank, instrument zero).

Recalibrate

Run linearity check

Check method specificity

NO

Are you satisfied with slope?

YES

Are you satisfied with intercept?

NO

☺

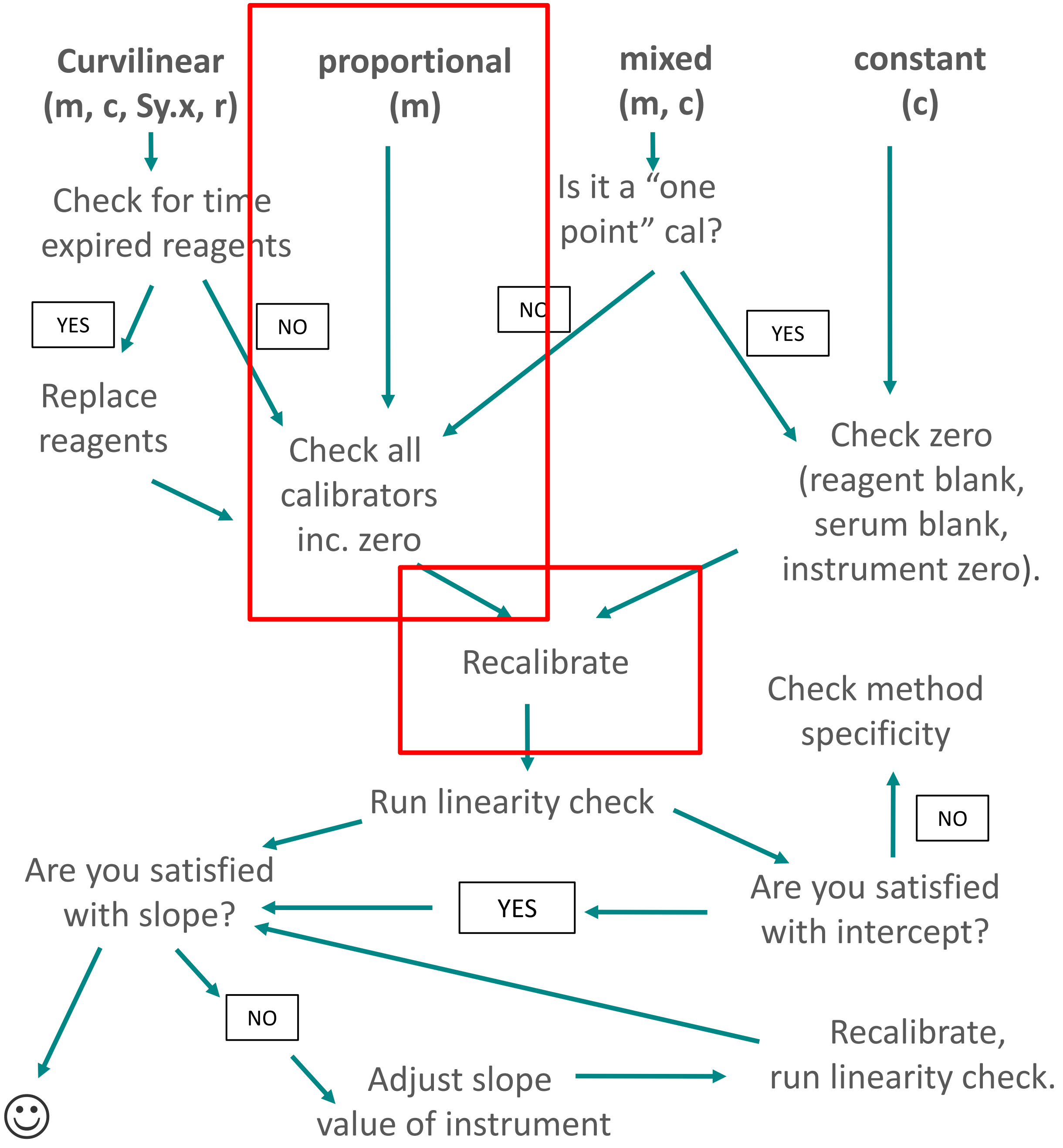
Adjust slope value of instrument

Recalibrate, run linearity check.

Pages 18-19 of SP-QL1-IntLabEQA

Problem Solving Flow Chart

INACCURACY



Curvilinear (m, c, Sy.x, r)

proportional (m)

mixed (m, c)

constant (c)

Check for time expired reagents

YES

NO

Replace reagents

Is it a "one point" cal?

NO

YES

Check all calibrators inc. zero

Check zero (reagent blank, serum blank, instrument zero).

Recalibrate

Check method specificity

Run linearity check

NO

Are you satisfied with slope?

YES

Are you satisfied with intercept?

NO

Recalibrate, run linearity check.

☺

Adjust slope value of instrument

Pages 18-19 of SP-QL1-IntLabEQA