Weqas
Unit 6, Parc Tŷ Glas
Llanishen, Cardiff, CF14 5DU

Tel: 02920 314750
Email: contact@weqas.com

Weqas | GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

EXTERNAL QUALITY ASSESSMENT

INTERNAL QUALITY CONTROL

REFERENCE MEASUREMENT SERVICES

EDUCATION & TRAINING

Weqas Connect EQA Report Interpretation

Gareth Davies

Summary of Talk

- Scheme Design
- Basic statistics & Error Detection
- How do we set Performance Specifications and Target Values?
- Weqas Connect Standard Report

Scheme Design

Common Report format (quantitative)

Ammonia
b123 Co-oximetry
Bile Acids
Bilirubin
Blood Gas
BNP
Cardiac Markers
Co-oximetry
CRP
ED Toxicology
Endocrine
fFN
Haematinics
HbA1c
Homocysteine
Immunosuppressants
Lipids
NT Pro BNP
pH Meter
Plasma Cardiac Markers
pO_2 Accuracy

pO2 Accuracy
POCT Creatinine
POCT CRP
POCT D-dimer
POCT Haemoglobin
POCT INR
POCT Urine ACR
Porphyrin
Pre-Eclampsia
Procalcitonin
Quantitative Faecal Hb
SARS-CoV-2 Ab
SARS-CoV-2 Ag
Serum ACE
Serum Chemistry
Serum hCG
Serum Indices
Therapeutic Drug Monitoring
Urine Chemistry
Urine Oxalate & Citrate

Why multiple samples is important

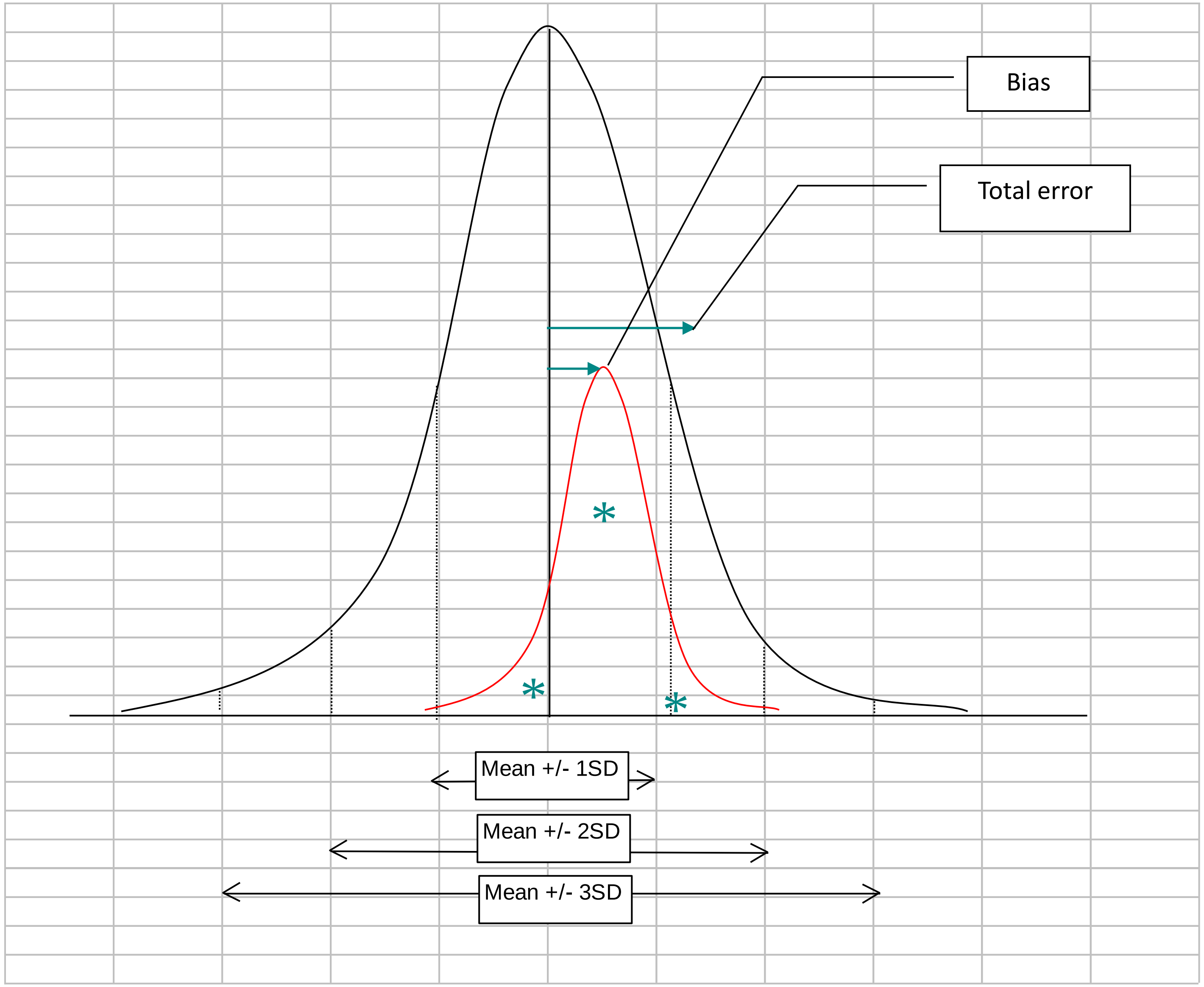
Identifies components of both Imprecision and Inaccuracy

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.

'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

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

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

Standard dev of residuals

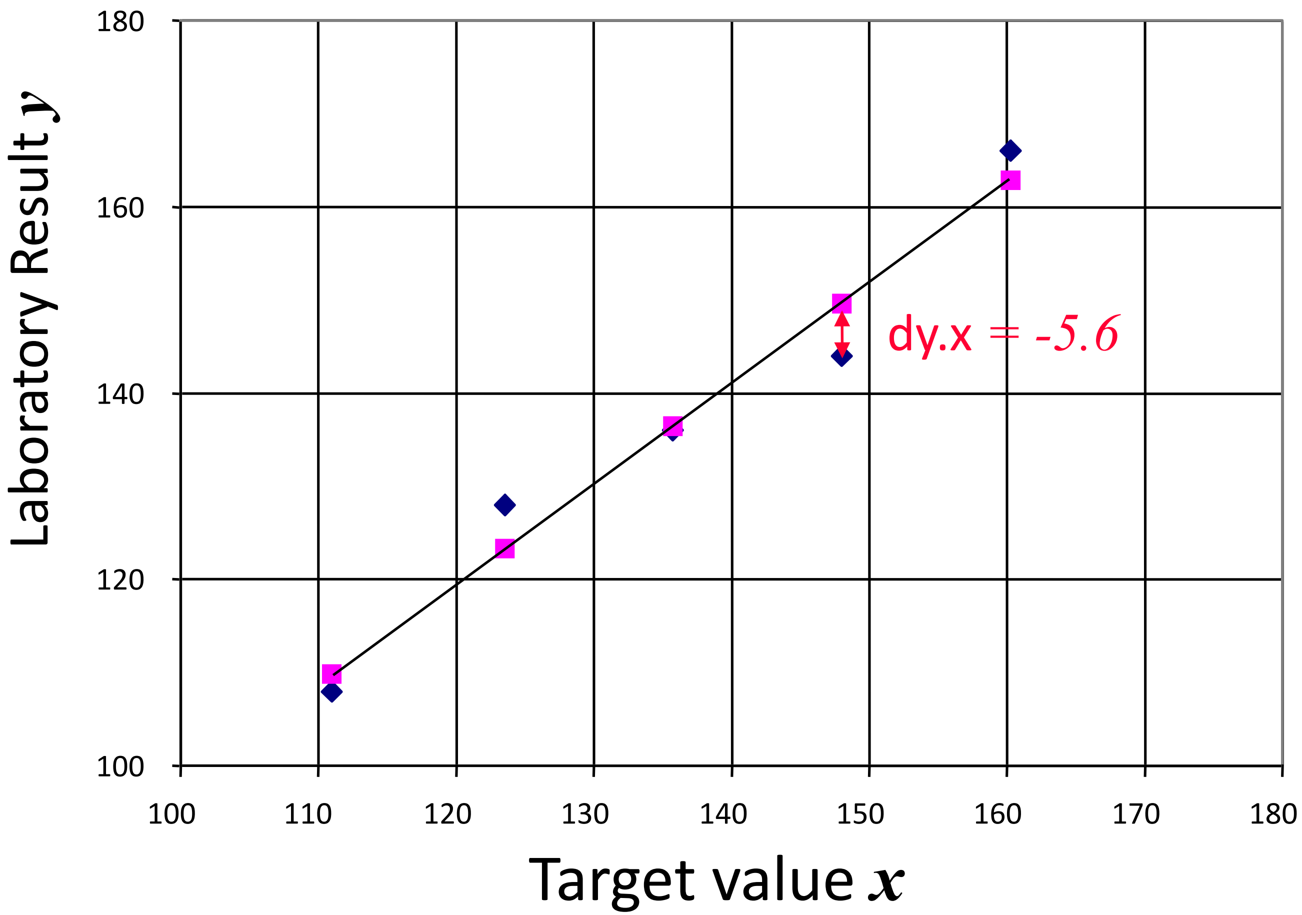
$$S_{y.x} = \sqrt{\frac{\Sigma\,(\tilde{y}-y)^2}{\text{d.f.}}}$$

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

◆

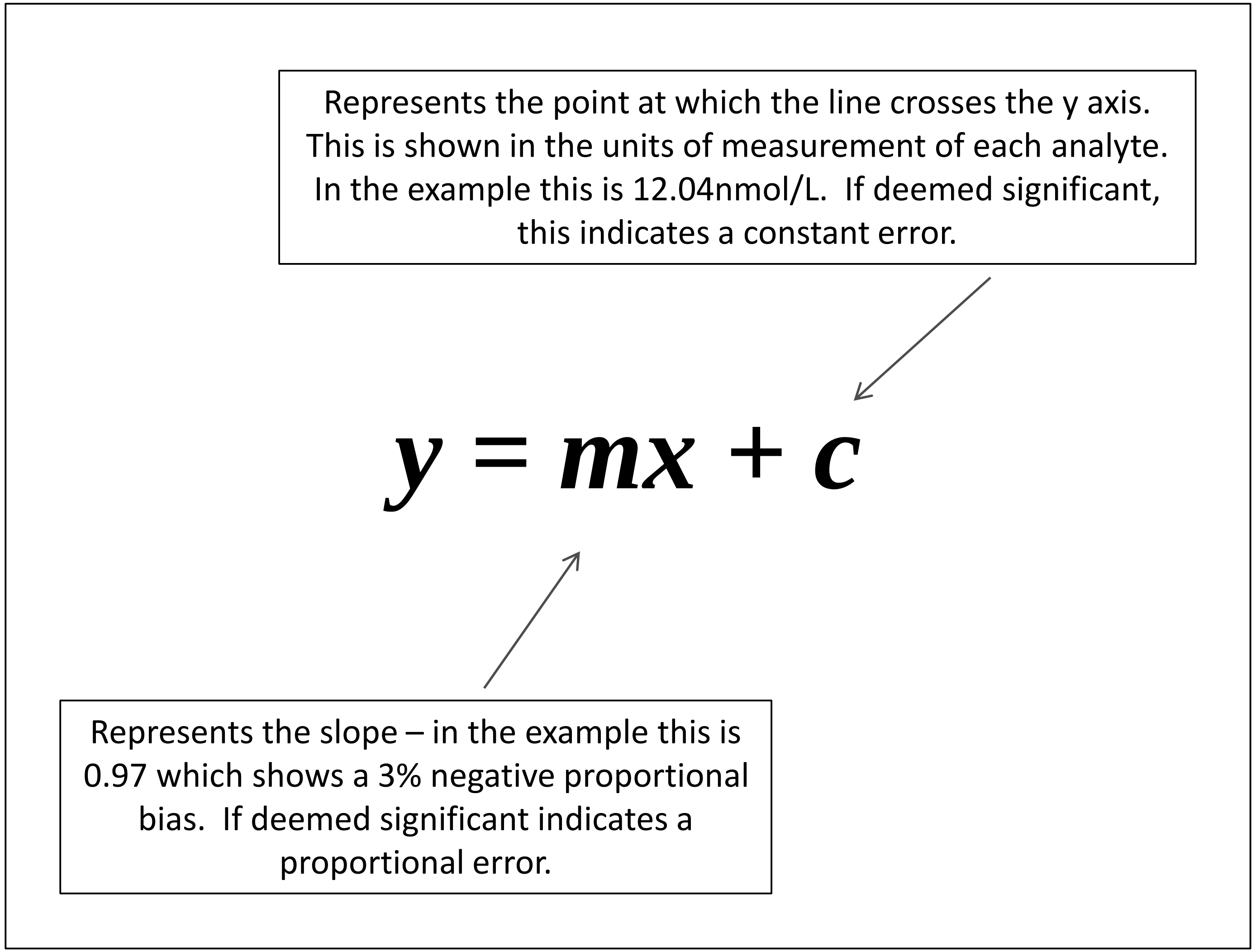
r = 0.9812
Sy.x= 4.1

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*

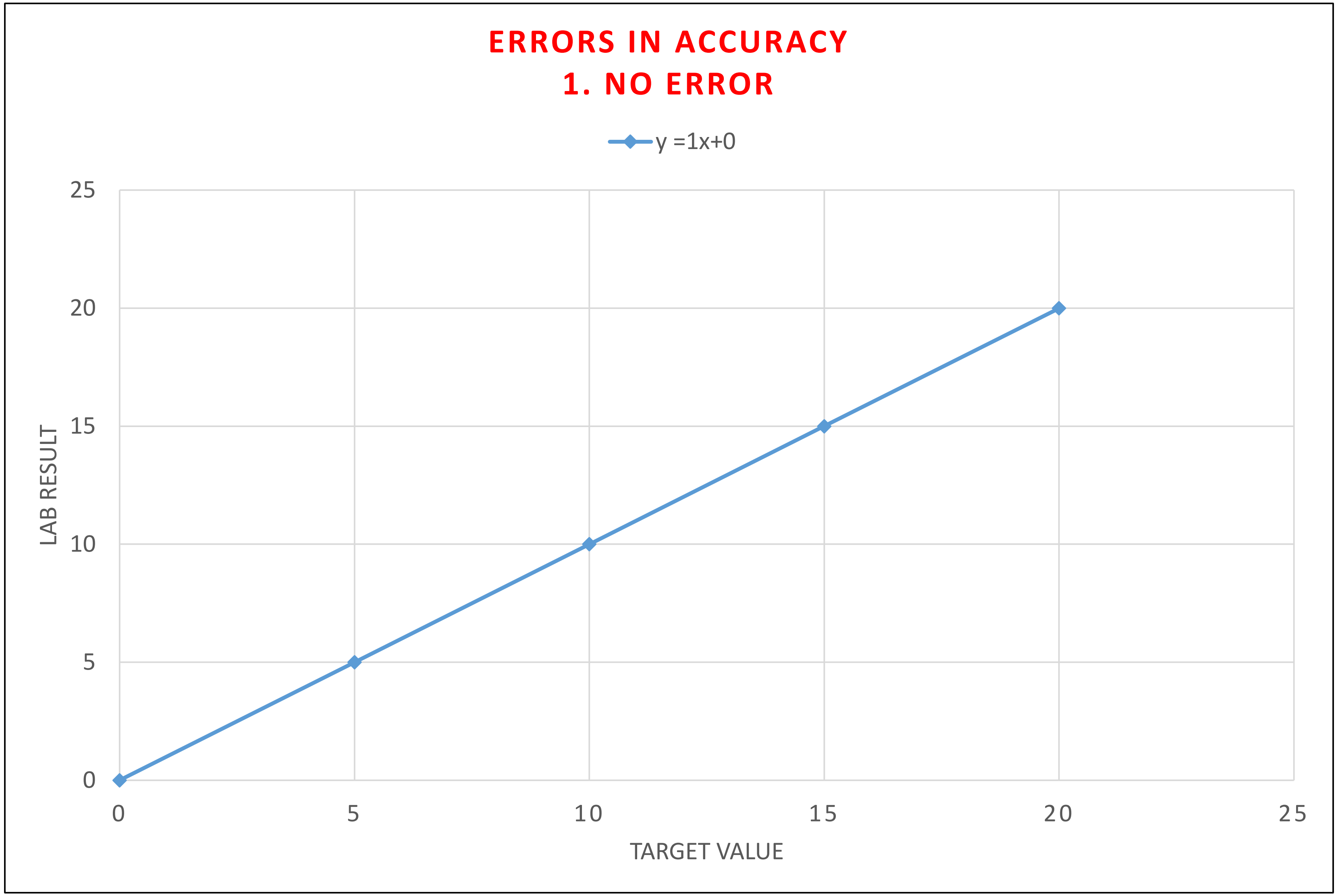
Interpretation of Inaccuracy



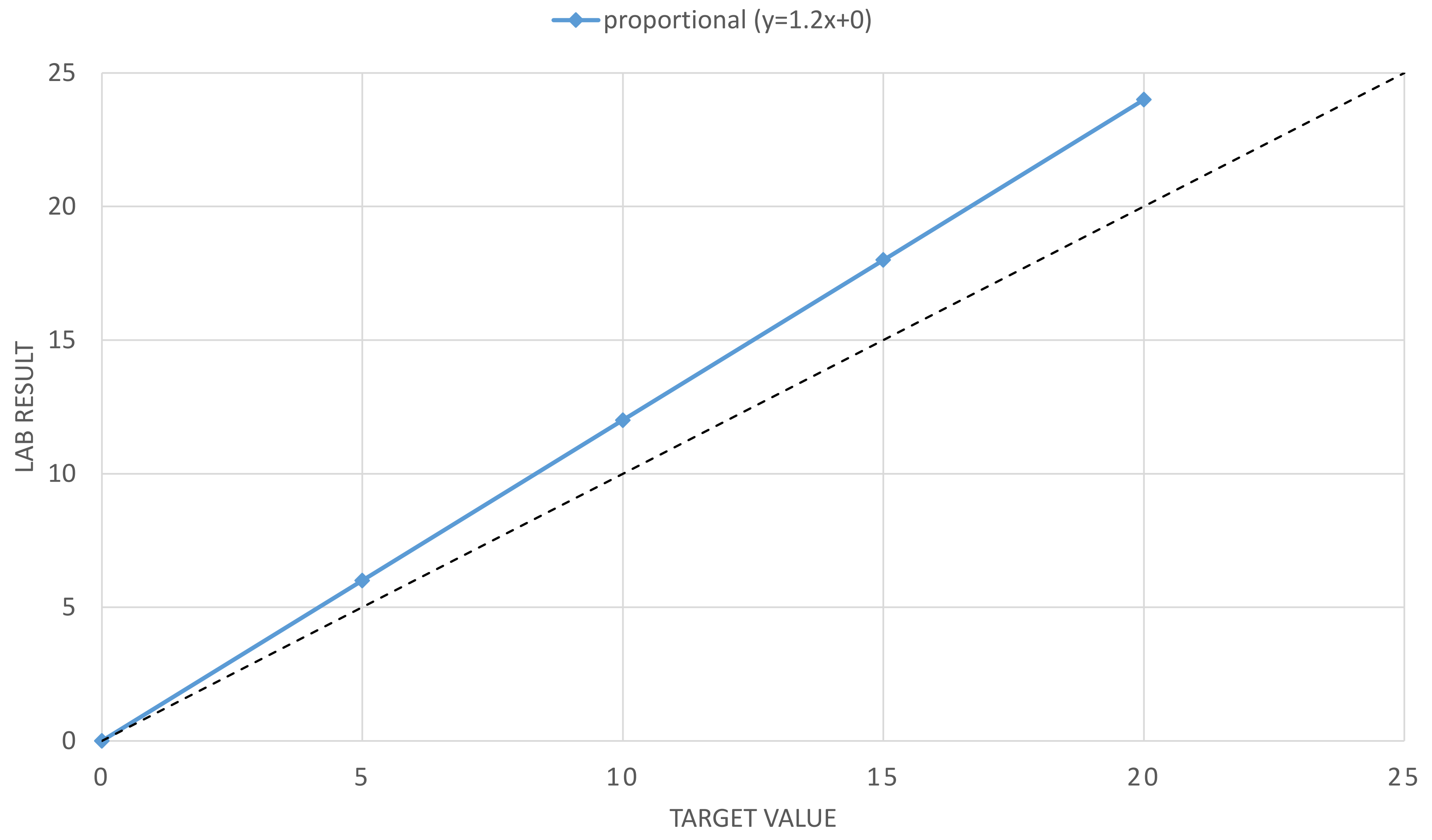
Represents the point at which the line crosses the y axis. This is shown in the units of measurement of each analyte. In the example this is 12.04nmol/L. If deemed significant, this indicates a constant error.

$$y = mx + c$$

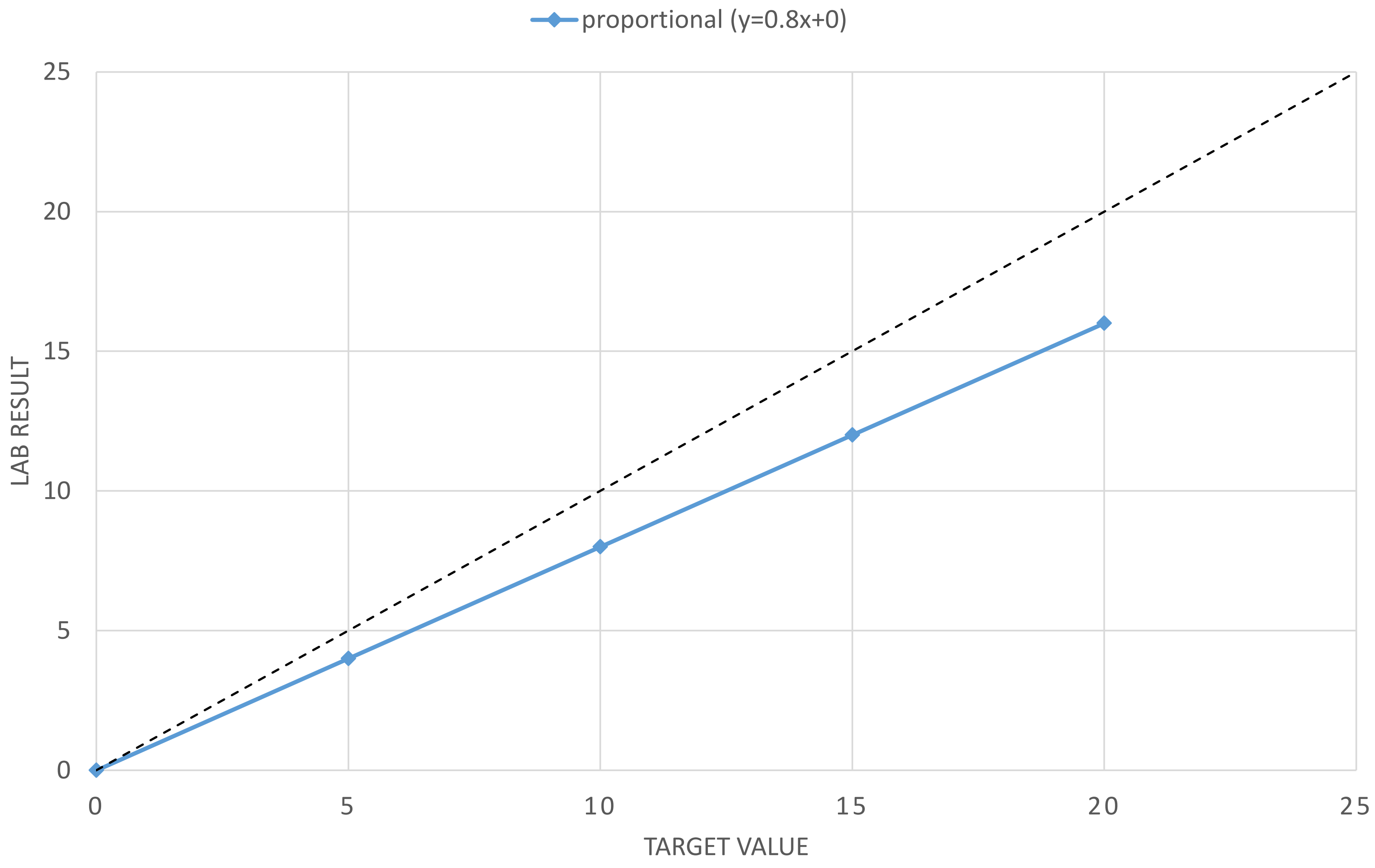
Represents the slope – in the example this is 0.97 which shows a 3% negative proportional bias. If deemed significant indicates a proportional error.


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

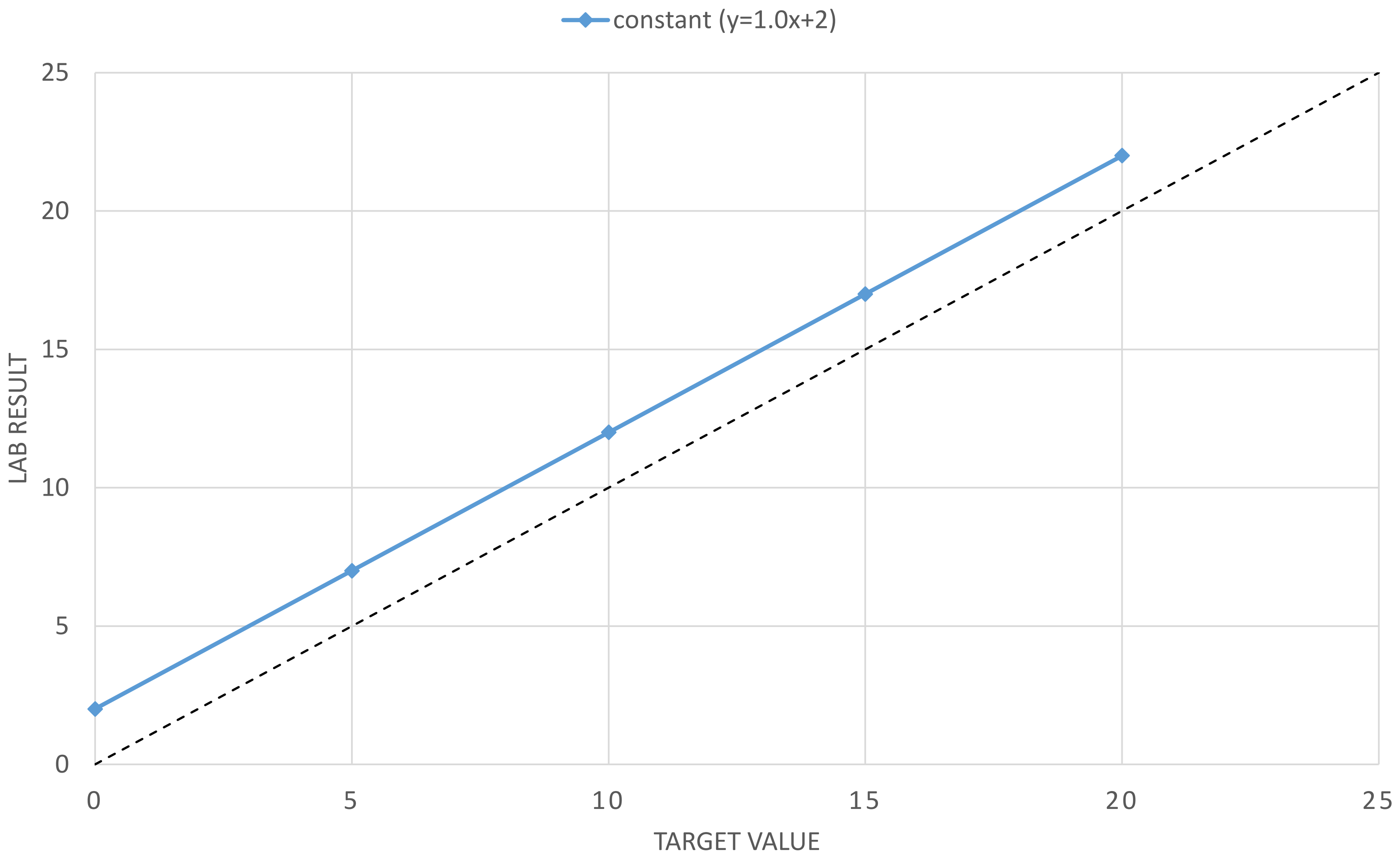
ERRORS IN ACCURACY
2. SYSTEMATIC PROPORTIONAL (POSITIVE BIAS)

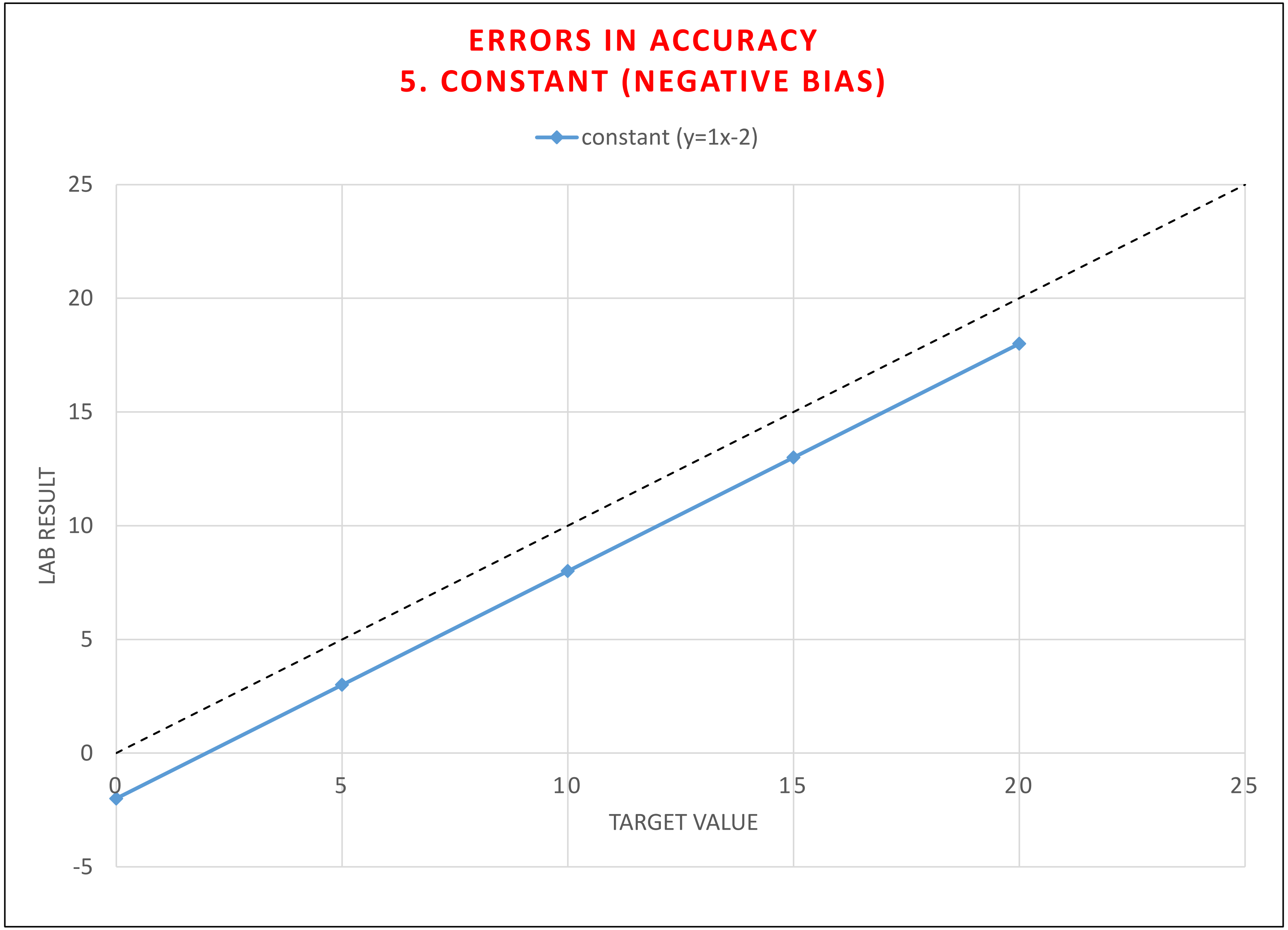


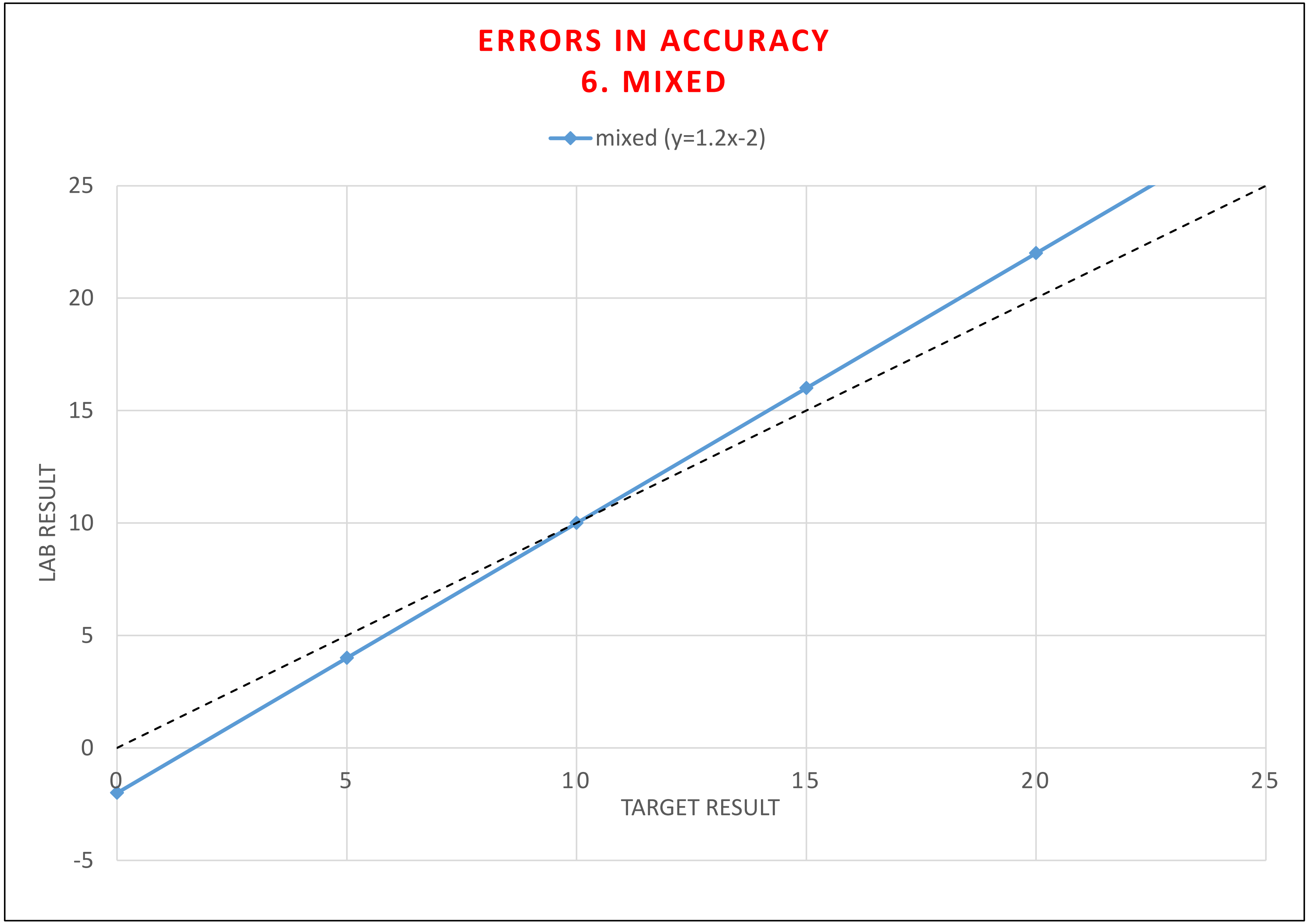
ERRORS IN ACCURACY
3. SYSTEMATIC PROPORTIONAL (NEGATIVE BIAS)

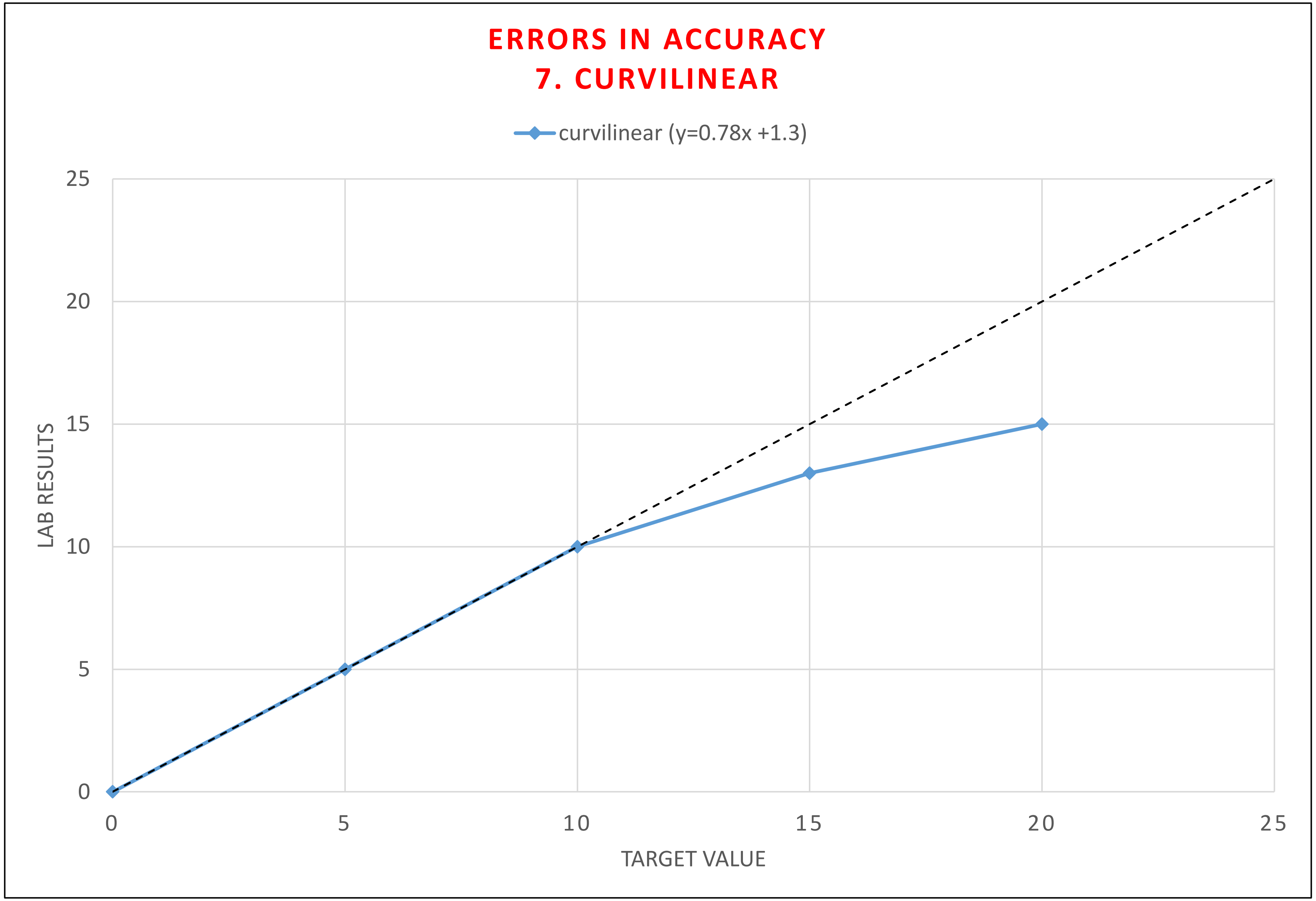


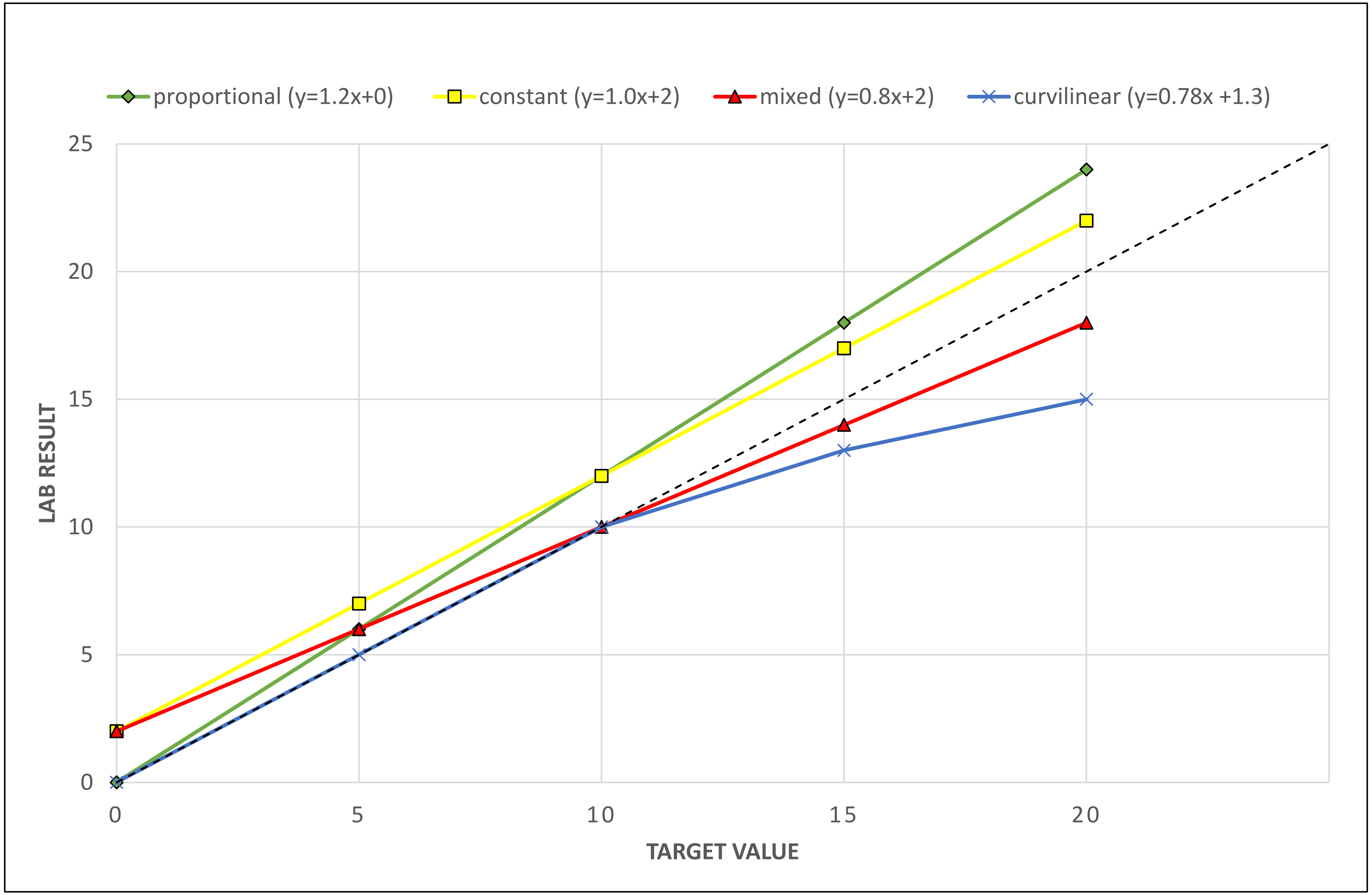
ERRORS IN ACCURACY
4. CONSTANT (POSITIVE BIAS)




ERRORS IN ACCURACY
5. CONSTANT (NEGATIVE BIAS)
constant (y=1x-2)
25
20
15
10
5
0
-5
LAB RESULT
0
5
10
15
20
25
TARGET VALUE


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
curvilinear (y=0.78x +1.3)
LAB RESULTS
25
20
15
10
5
0
0
5
10
15
20
25
TARGET VALUE


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

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

Generation of Reference Target Values

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

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

Reference Methods

Flame Atomic Absorption/ Emission Spectrometry

- Sodium, Potassium, Calcium
- Magnesium, Lithium

IFCC Enzymes

- AST, ALT, LDH, GGT, CK, Amylase

HPLC

- Homocysteine
- HbA1c **

** Provided by IFCC Ref lab, Netherlands

LC-MS/MS

- Testosterone
- Cortisol

IDGC-MS

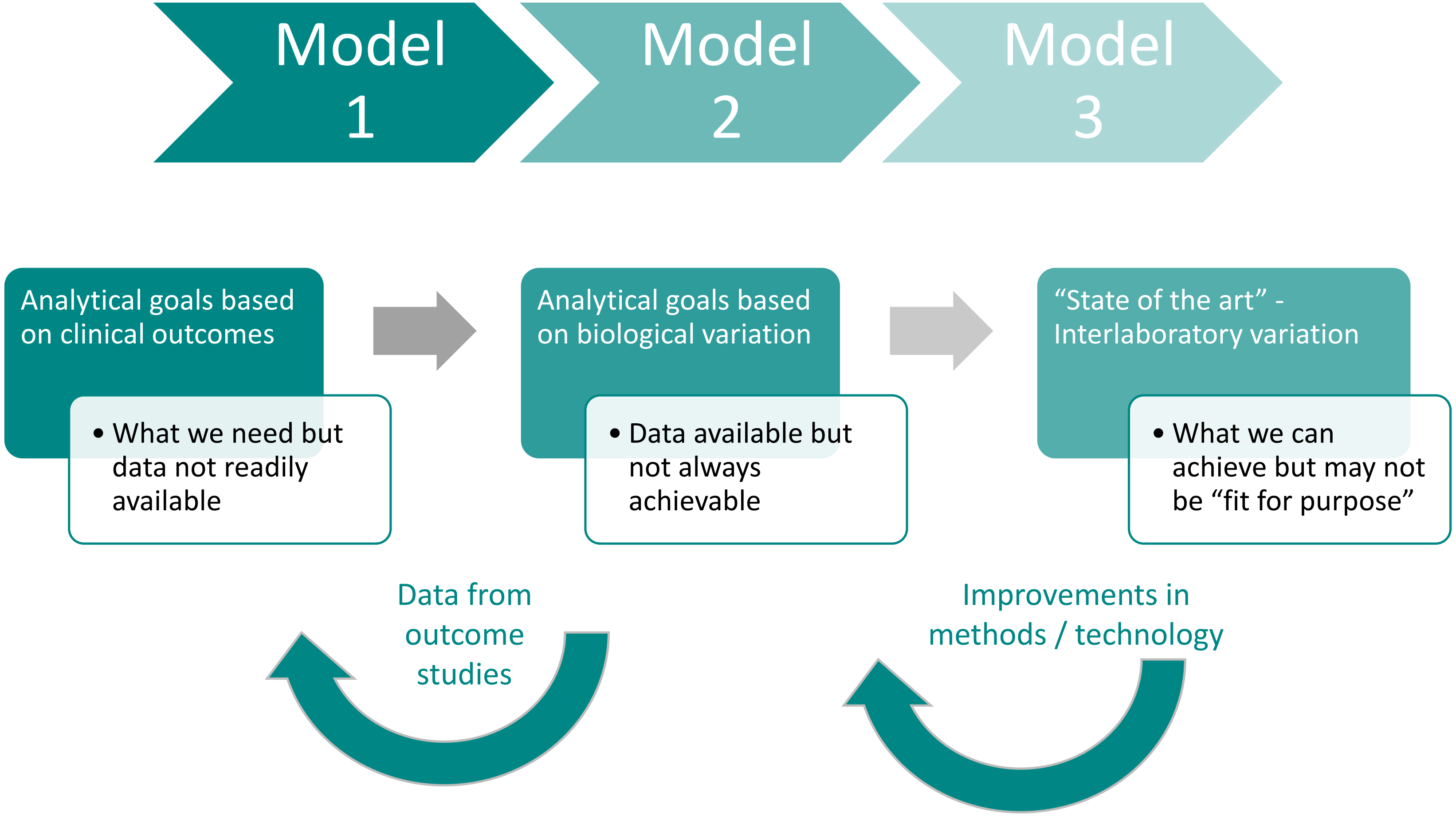
- 17ß-Oestradiol
- Progesterone
- Bile Acids
- Creatinine
- Cholesterol
- Glucose
- Urate
- Triglyceride
- HDL *

* Currently provided by CDC lab Rotterdam and WEQAS

Determining analytical quality specifications

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

Analytical goal Hierarchy



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

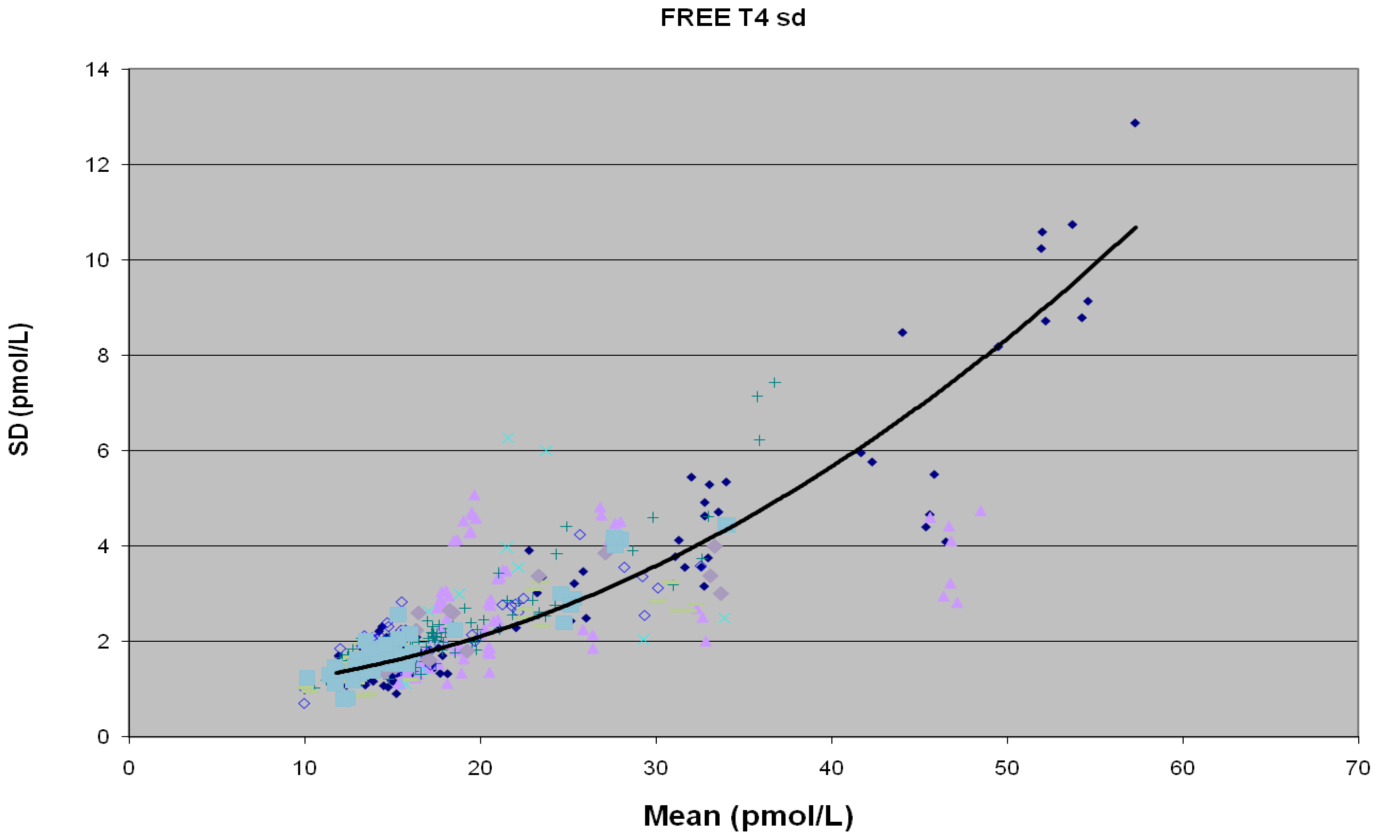
- What we can achieve but may not be "fit for purpose"

Data from outcome studies

Improvements in methods / technology

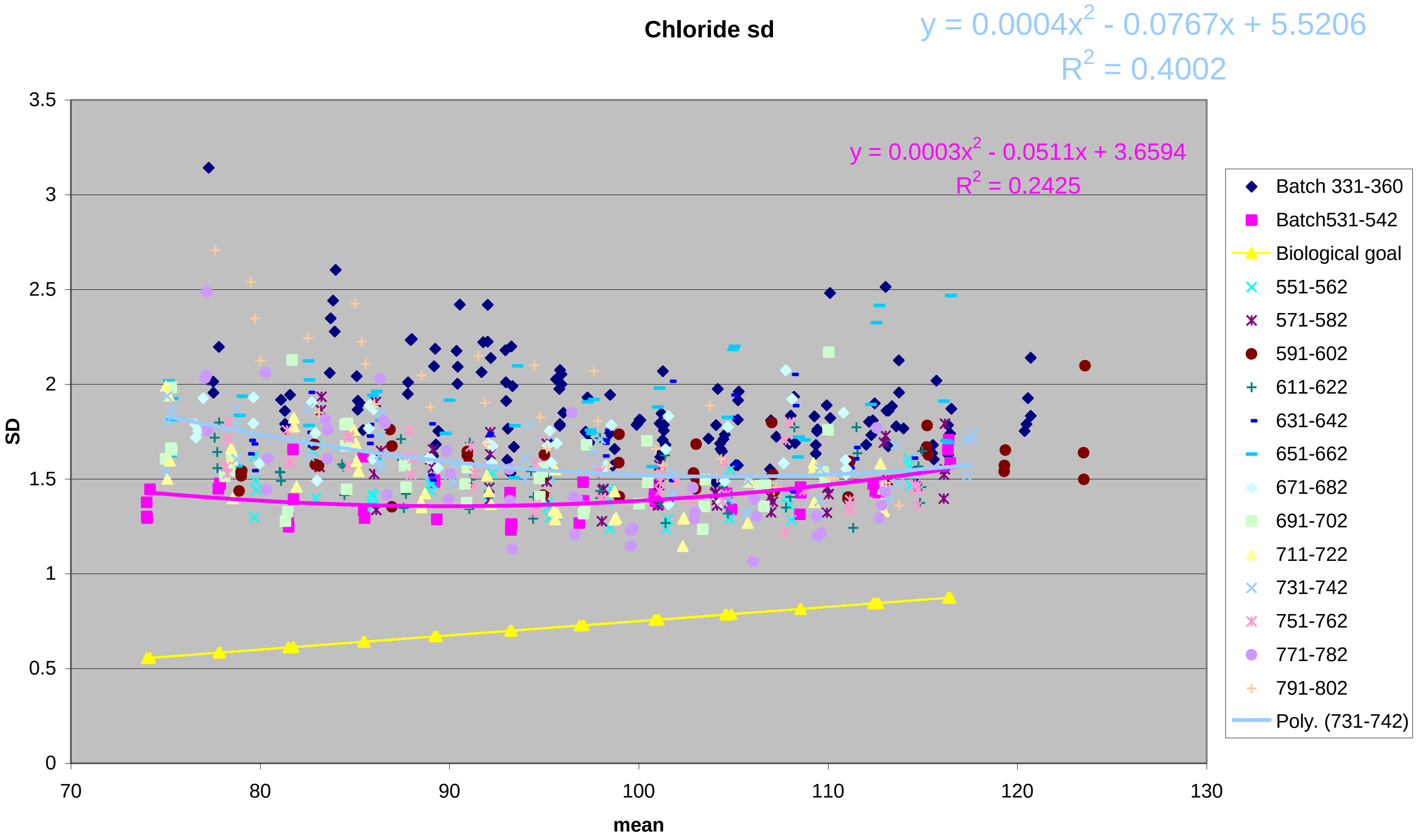
Interlaboratory variation

FT4



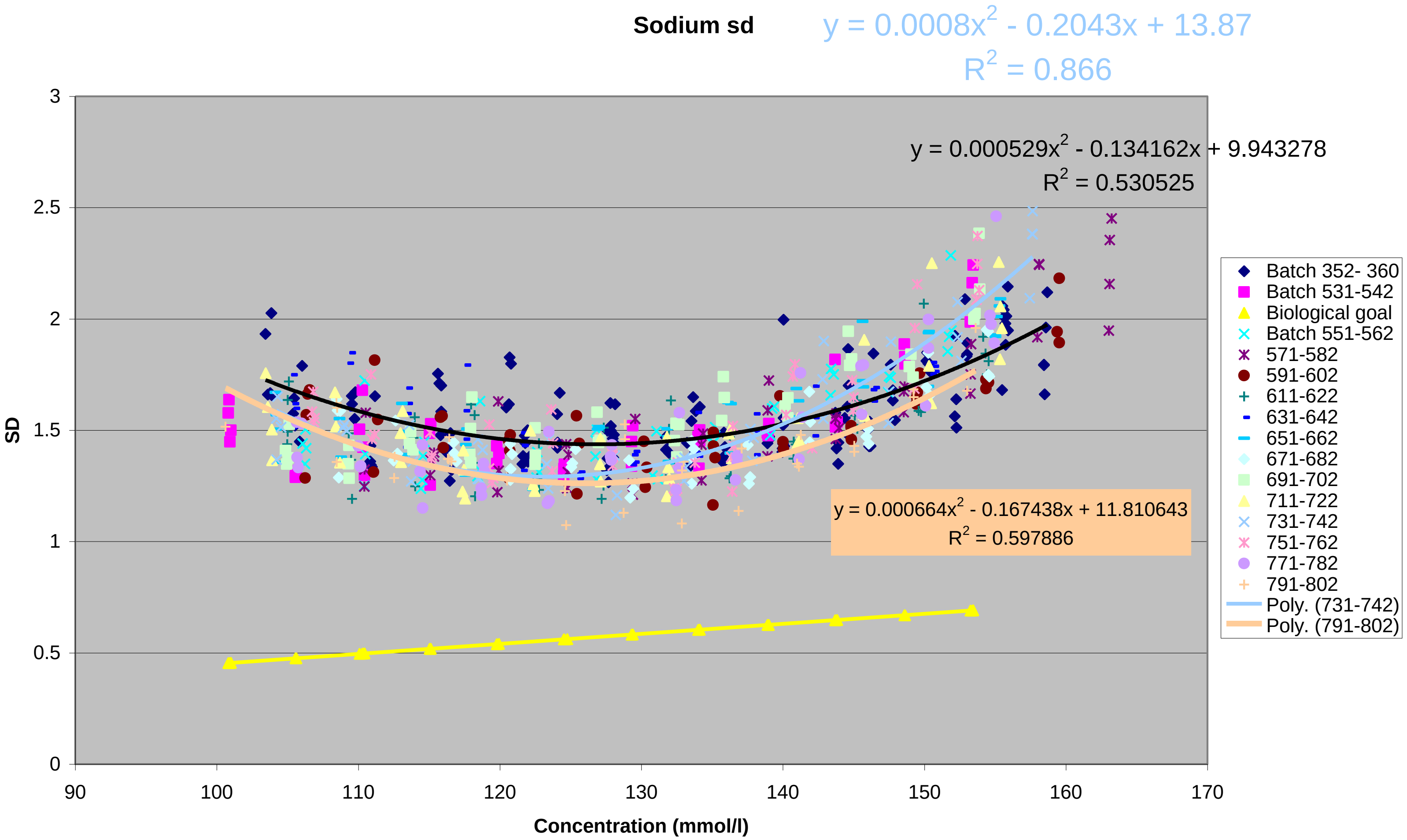
Relationship of analyte conc. to SD follows a polynomial equation for most analytes and is non linear therefore using fixed % TE is not appropriate

“State of the art” v Biology



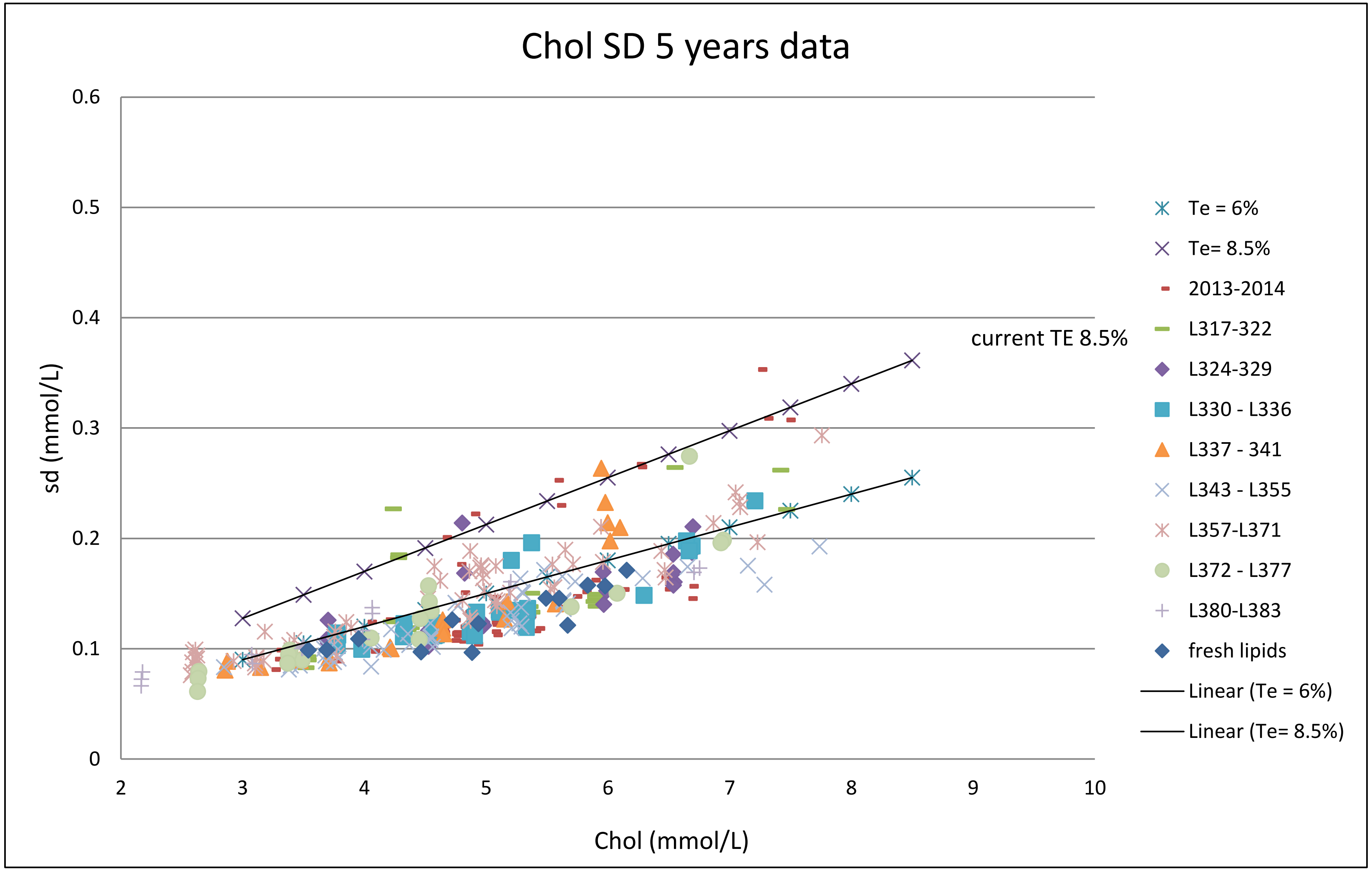
Biological goals not achievable. Performance has not improved over time.

"State of the art" v Biology



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

“State of the art” v Biology



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

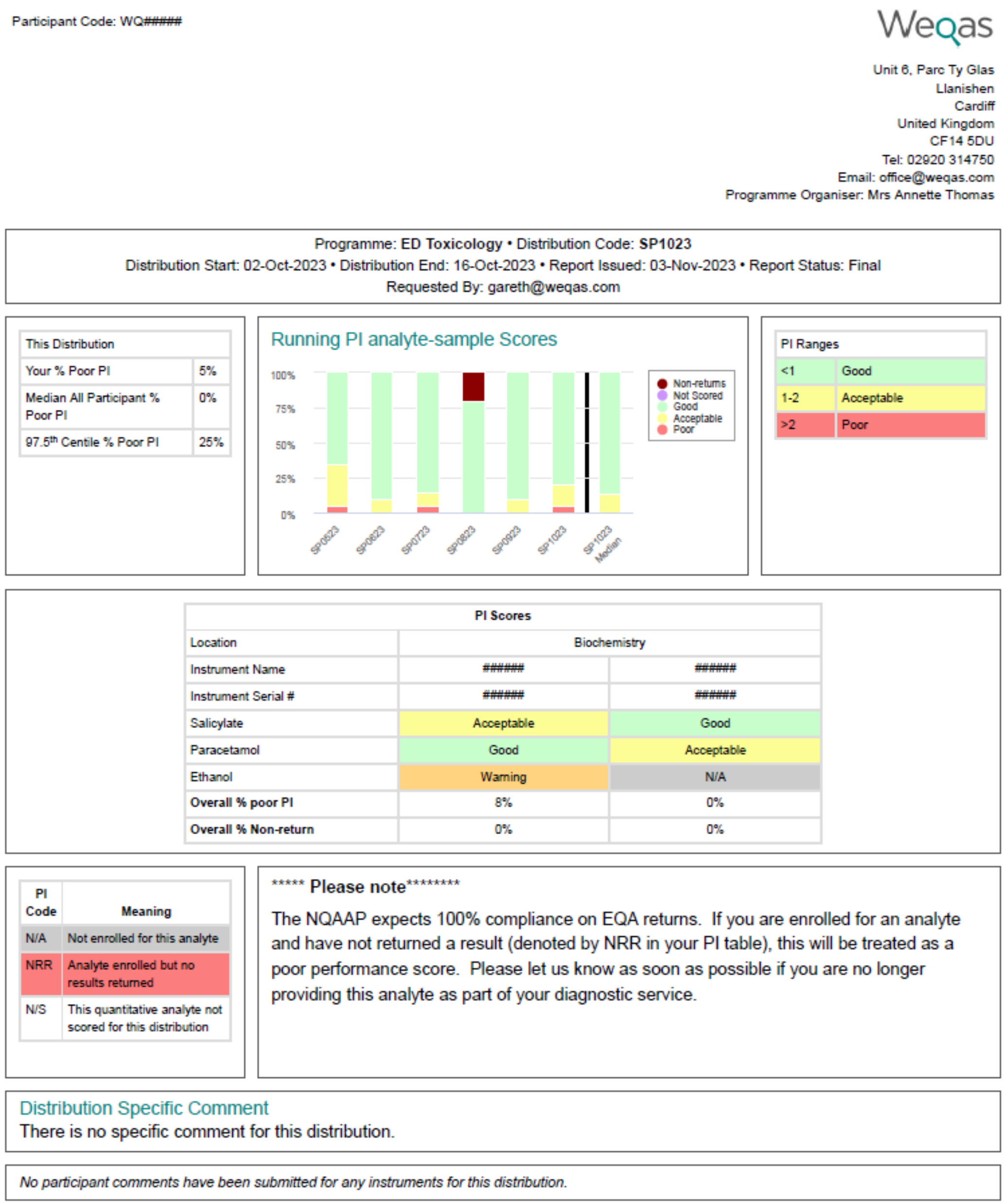
Sigma metric: $[(\mathrm{TE}_{a} - \mathrm{bias}_{obs})/s_{obs}]$

Total Allowable Error as defined by MAPS

Laboratory bias at critical level

Within run CV (%)

Standard Quantitative Report



Participant Code: WQ#####

Unit 6, Parc Ty Glas
Llanishen
Cardiff
United Kingdom
CF14 5DU
Tel: 02920 314750
Email: office@weqas.com
Programme Organiser: Mrs Annette Thomas

Programme: **ED Toxicology** • Distribution Code: **SP1023**
Distribution Start: 02-Oct-2023 • Distribution End: 16-Oct-2023 • Report Issued: 03-Nov-2023 • Report Status: Final
Requested By: gareth@weqas.com

This Distribution	
Your % Poor PI	5%
Median All Participant % Poor PI	0%
97.5th Centile % Poor PI	25%

Running PI analyte-sample Scores

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

PI Scores		
Location	Biochemistry	
Instrument Name	######	######
Instrument Serial #	######	######
Salicylate	Acceptable	Good
Paracetamol	Good	Acceptable
Ethanol	Warning	N/A
Overall % poor PI	8%	0%
Overall % Non-return	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.

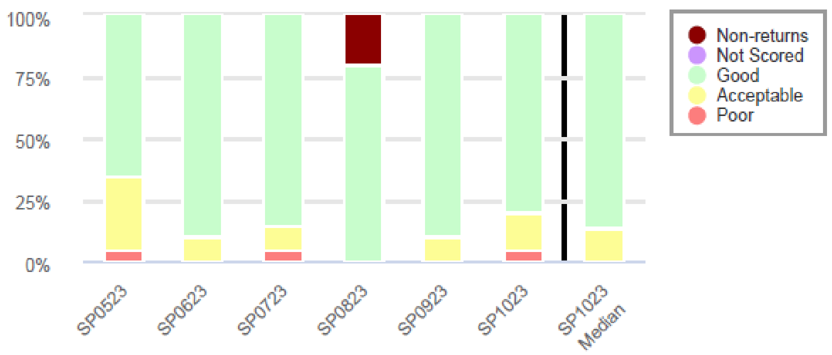
Participant Code: WQ#####

Unit 6, Parc Ty Glas
Llanishen
Cardiff
United Kingdom
CF14 5DU
Tel: 02920 314750
Email: office@weqas.com
Programme Organiser: Mrs Annette Thomas

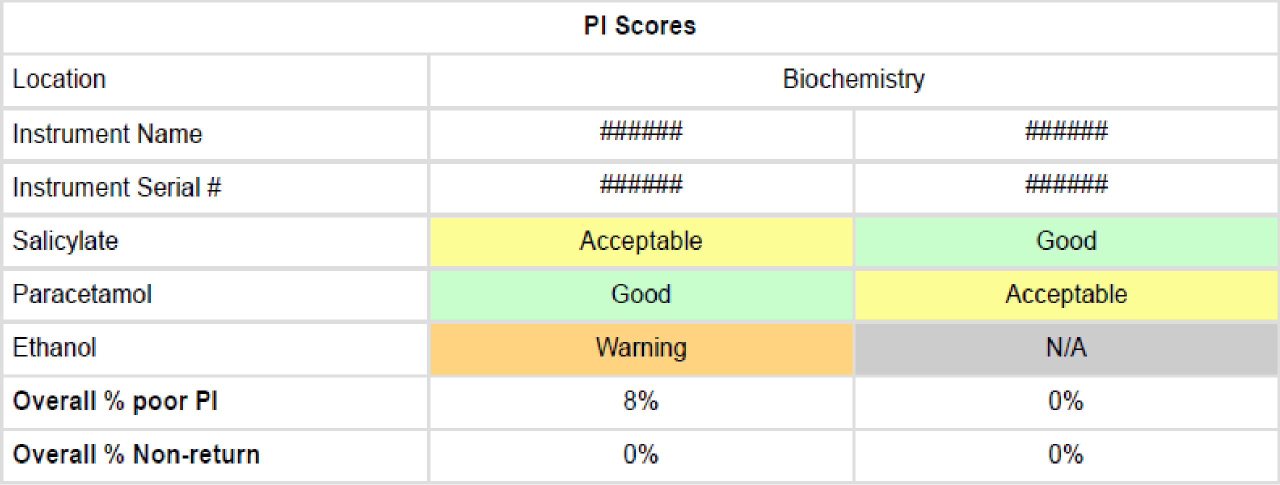
Programme: **ED Toxicology** • Distribution Code: **SP1023**
Distribution Start: 02-Oct-2023 • Distribution End: 16-Oct-2023 • Report Issued: 03-Nov-2023 • Report Status: Final
Requested By: gareth@weqas.com

This Distribution	
Your % Poor PI	5%
Median All Participant % Poor PI	0%
97.5th Centile % Poor PI	25%

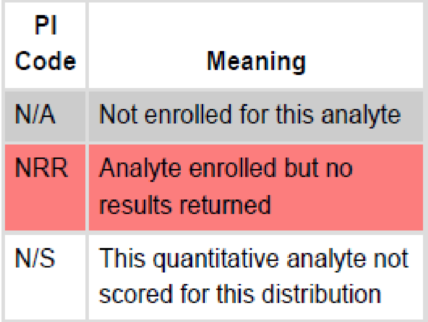
Running PI analyte-sample Scores



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



PI Scores		
Location	Biochemistry	
Instrument Name	######	######
Instrument Serial #	######	######
Salicylate	Acceptable	Good
Paracetamol	Good	Acceptable
Ethanol	Warning	N/A
Overall % poor PI	8%	0%
Overall % Non-return	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**********

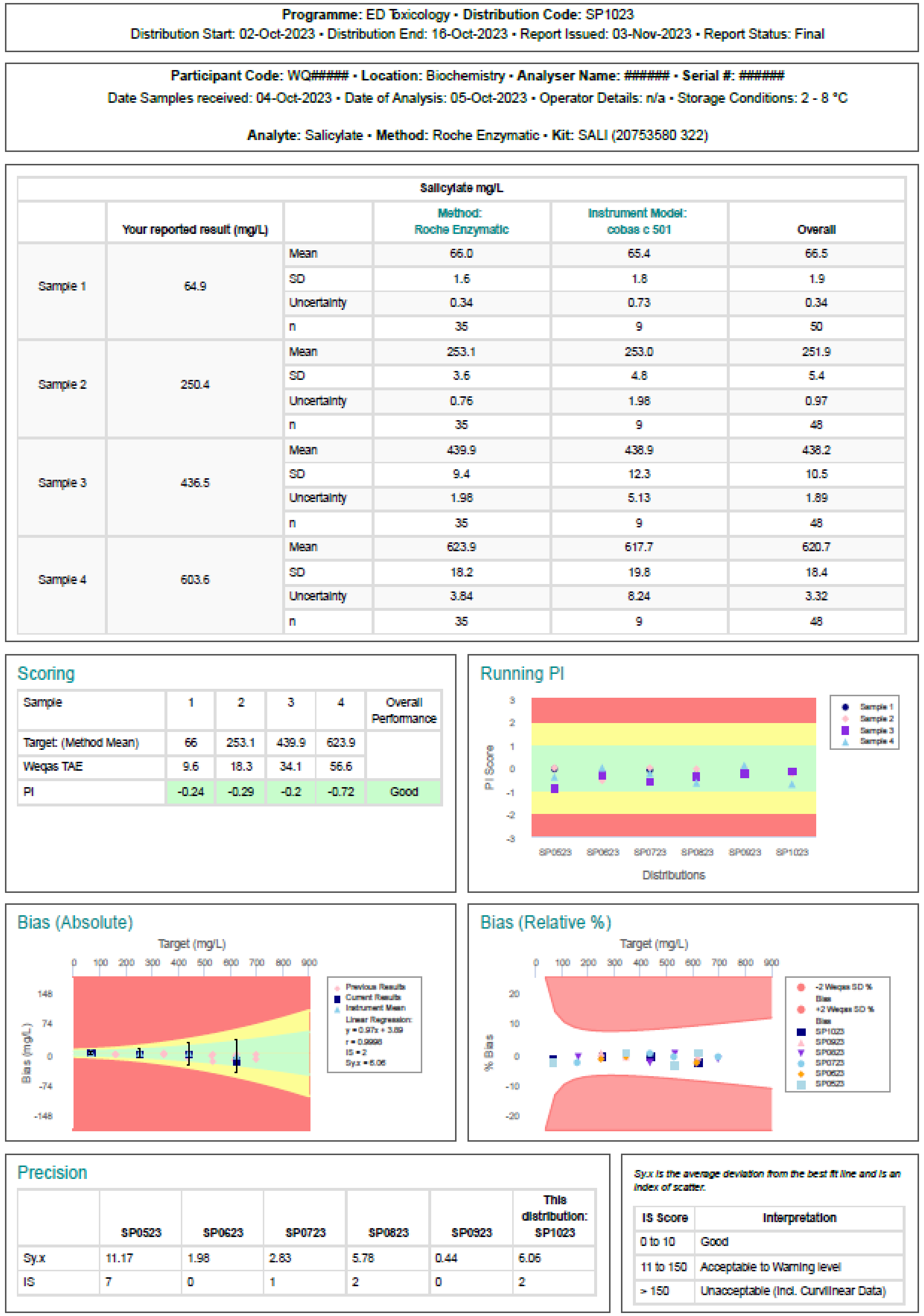
The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by NRR in your PI table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic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

Distribution Specific Comment

There is no specific comment for this distribution.

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

Weqas



Programme: ED Toxicology • **Distribution Code:** SP1023
Distribution Start: 02-Oct-2023 • Distribution End: 16-Oct-2023 • Report Issued: 03-Nov-2023 • Report Status: Final

Participant Code: WQ##### • **Location:** Biochemistry • **Analyser Name:** ###### • **Serial #:** ######
Date Samples received: 04-Oct-2023 • Date of Analysis: 05-Oct-2023 • Operator Details: n/a • Storage Conditions: 2 - 8 °C

Analyte: Salicylate • **Method:** Roche Enzymatic • **Kit:** SALI (20753580 322)

Salicylate mg/L

	Your reported result (mg/L)		Method: Roche Enzymatic	Instrument Model: cobas c 501	Overall
Sample 1	64.9	Mean	66.0	65.4	66.5
		SD	1.6	1.8	1.9
		Uncertainty	0.34	0.73	0.34
		n	35	9	50
Sample 2	250.4	Mean	253.1	253.0	251.9
		SD	3.6	4.8	5.4
		Uncertainty	0.76	1.98	0.97
		n	35	9	48
Sample 3	436.5	Mean	439.9	438.9	438.2
		SD	9.4	12.3	10.5
		Uncertainty	1.98	5.13	1.89
		n	35	9	48
Sample 4	603.6	Mean	623.9	617.7	620.7
		SD	18.2	19.8	18.4
		Uncertainty	3.84	8.24	3.32
		n	35	9	48

Scoring

Sample	1	2	3	4	Overall Performance
Target (Method Mean)	66	253.1	439.9	623.9	
Weqas TAE	9.6	18.3	34.1	56.6	
PI	-0.24	-0.29	-0.2	-0.72	Good

Running PI

Bias (Absolute)

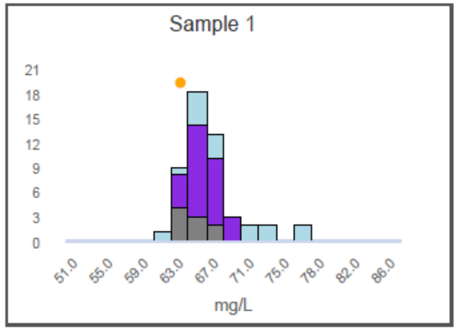
Bias (Relative %)

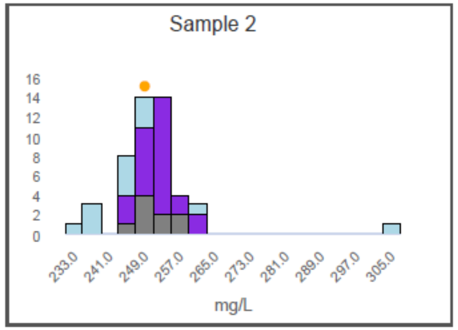
Precision

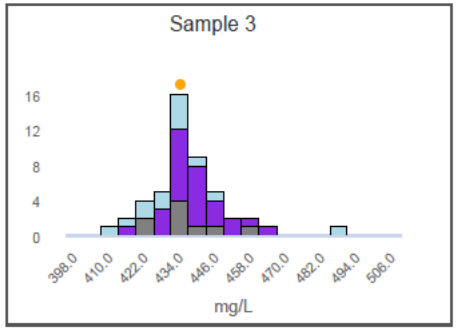
	SP0523	SP0623	SP0723	SP0823	SP0923	This distribution: SP1023
Sy.x	11.17	1.98	2.83	5.78	0.44	6.06
IS	7	0	1	2	0	2

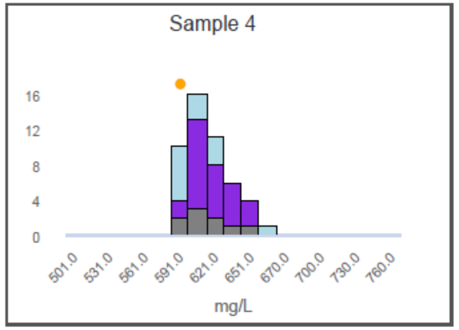
Sy.x is the average deviation from the best fit line and is an index of scatter.

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









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

Method Summary

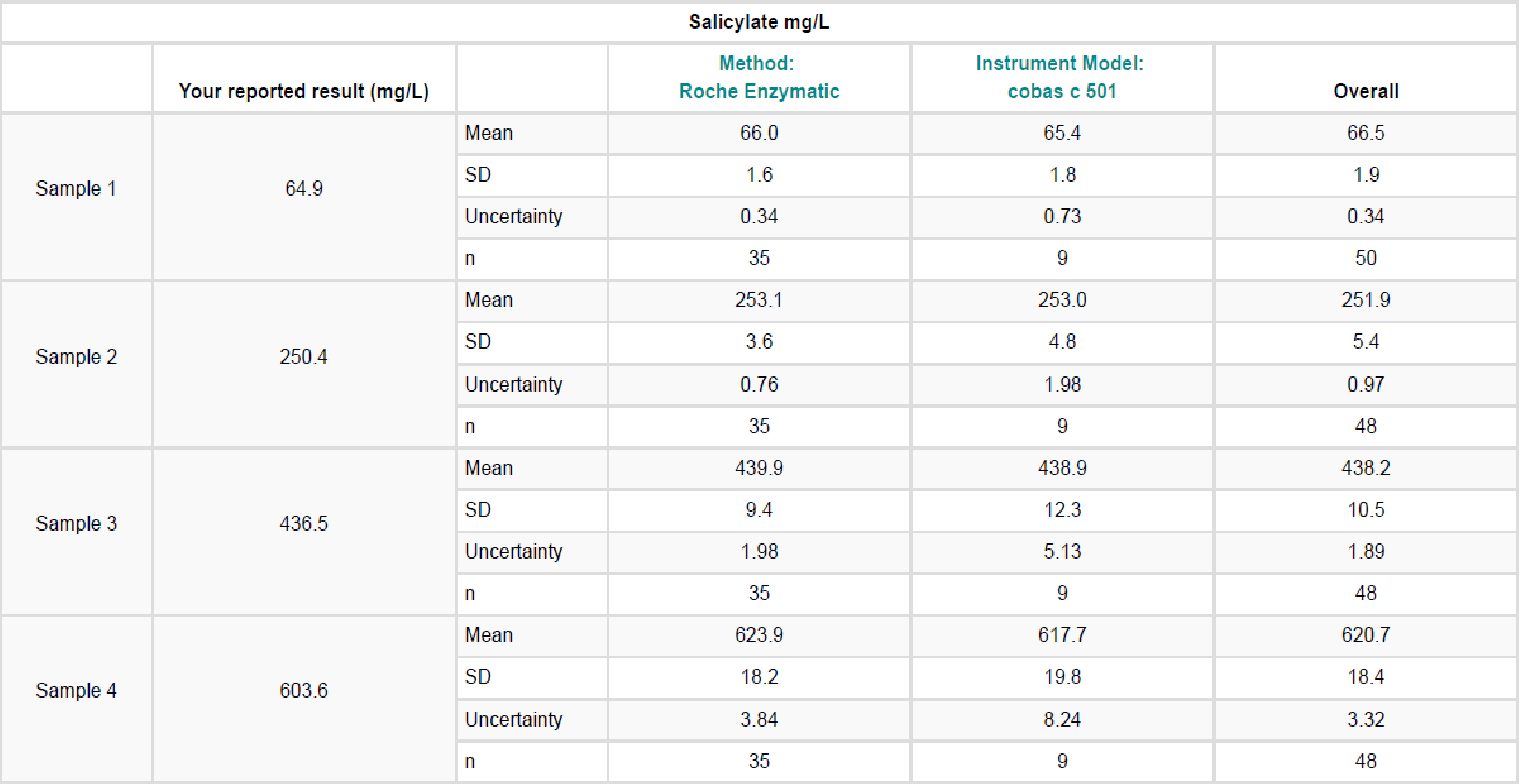
SP1023	Sample 1		Sample 2		Sample 3		Sample 4	
Method Name	**Mean**	**CV%**	**Mean**	**CV%**	**Mean**	**CV%**	**Mean**	**CV%**
CLS Enzymatic (n=1)	67.1	0.0	250.7	0.0	448.9	0.0	632.9	0.0
Emit tox Salicylic Acid (n=9)	68.1	6.0	250.1	4.5	435.4	1.7	614.7	2.9
Roche Enzymatic (n=35)	**66.0**	**2.4**	**253.1**	**1.4**	**439.9**	**2.1**	**623.9**	**2.9**
Siemens Enzymatic (n=5)	70.5	10.7	240.3	3.4	422.8	0.2	601.8	1.1

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

Participant Code: WQ##### • **Location:** Biochemistry • **Analyser Name:** ###### • **Serial #:** ######

Date Samples received: 04-Oct-2023 • Date of Analysis: 05-Oct-2023 • Operator Details: n/a • Storage Conditions: 2 - 8 °C

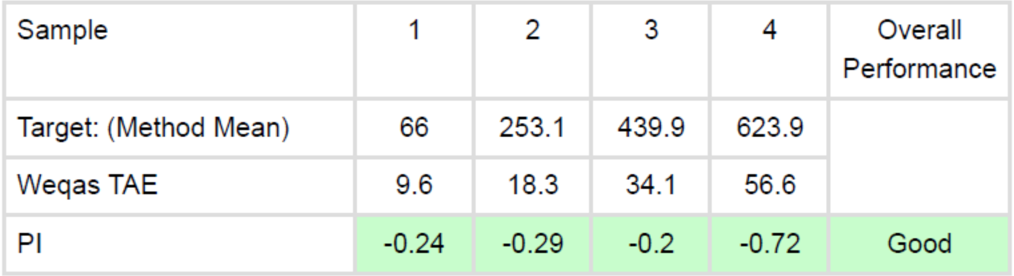
Analyte: Salicylate • **Method:** Roche Enzymatic • **Kit:** SALI (20753580 322)



Salicylate mg/L

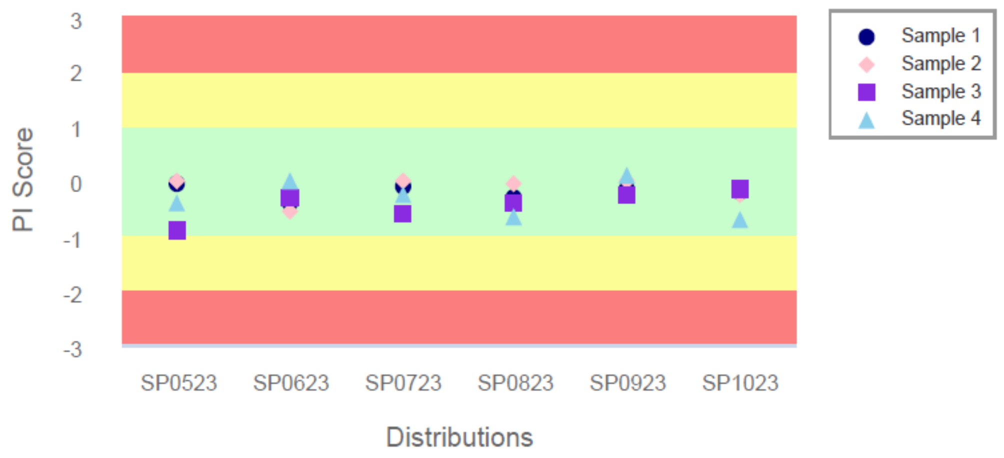
	Your reported result (mg/L)		Method: Roche Enzymatic	Instrument Model: cobas c 501	Overall
Sample 1	64.9	Mean	66.0	65.4	66.5
		SD	1.6	1.8	1.9
		Uncertainty	0.34	0.73	0.34
		n	35	9	50
Sample 2	250.4	Mean	253.1	253.0	251.9
		SD	3.6	4.8	5.4
		Uncertainty	0.76	1.98	0.97
		n	35	9	48
Sample 3	436.5	Mean	439.9	438.9	438.2
		SD	9.4	12.3	10.5
		Uncertainty	1.98	5.13	1.89
		n	35	9	48
Sample 4	603.6	Mean	623.9	617.7	620.7
		SD	18.2	19.8	18.4
		Uncertainty	3.84	8.24	3.32
		n	35	9	48

Scoring

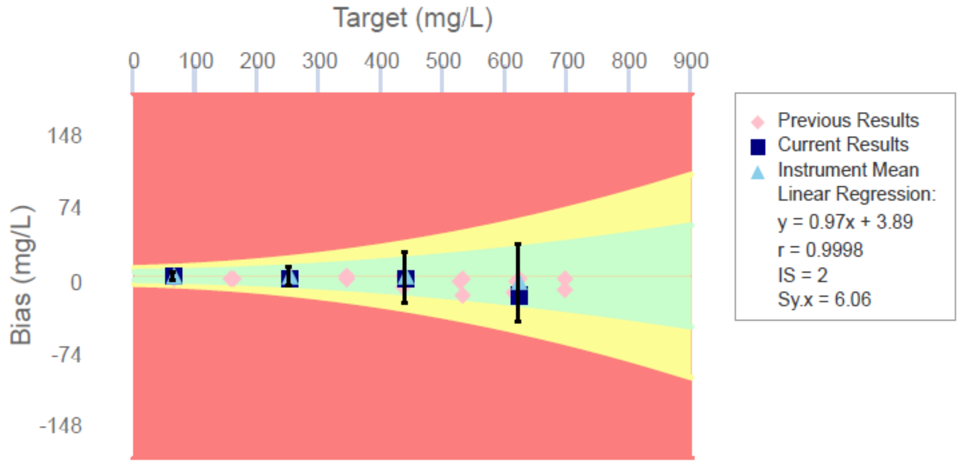


Sample	1	2	3	4	Overall Performance
Target: (Method Mean)	66	253.1	439.9	623.9	
Weqas TAE	9.6	18.3	34.1	56.6	
PI	-0.24	-0.29	-0.2	-0.72	Good

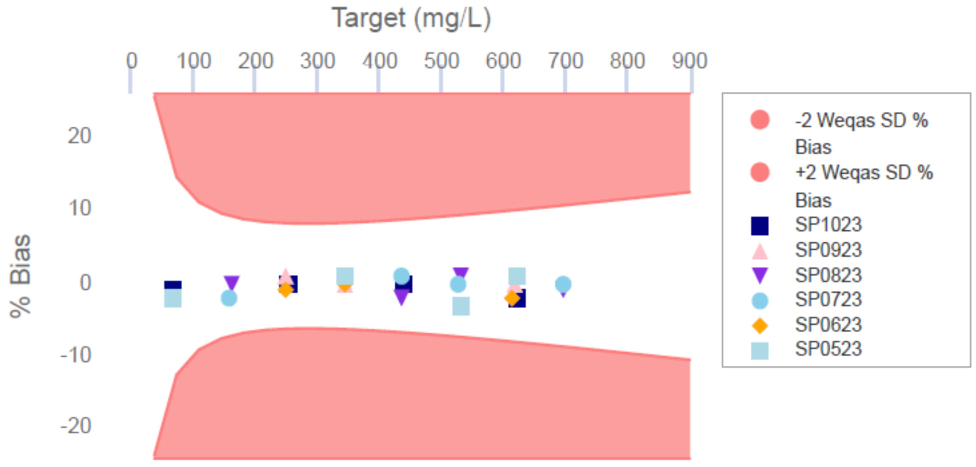
Running PI

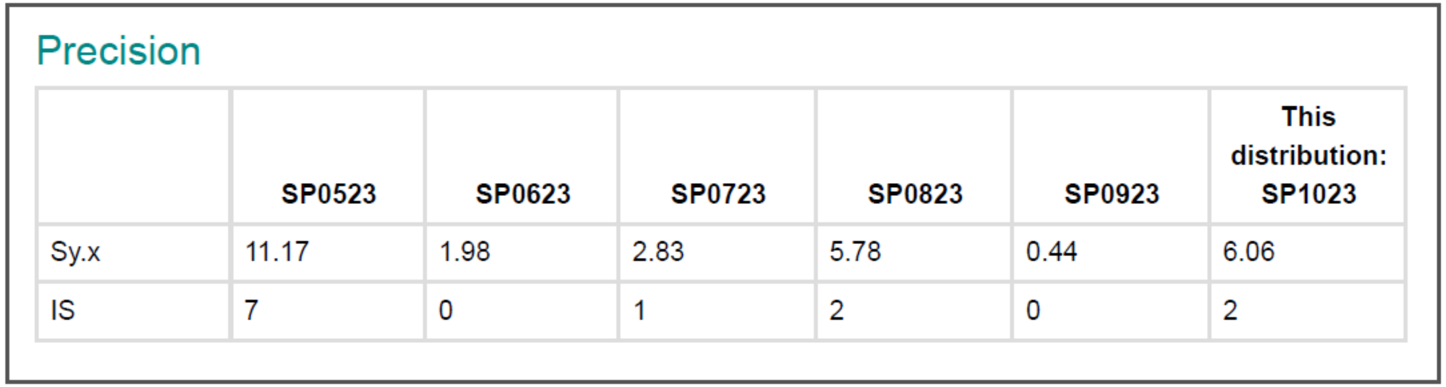


Bias (Absolute)



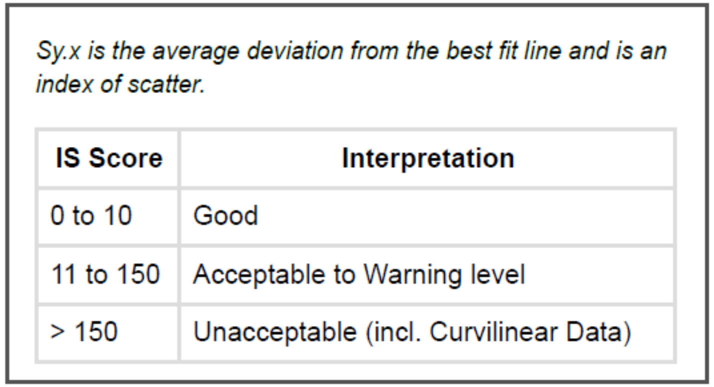
Bias (Relative %)





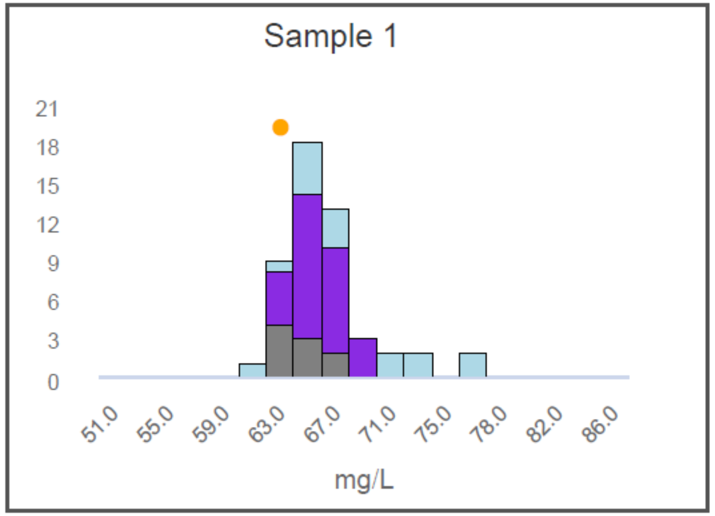
Precision

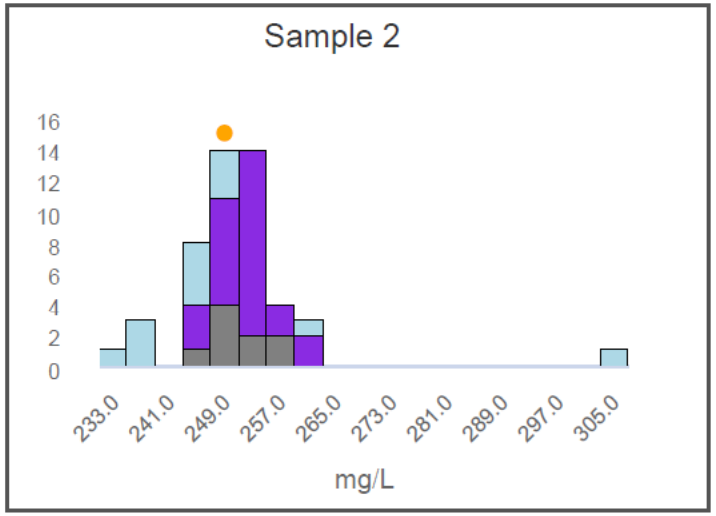
	SP0523	SP0623	SP0723	SP0823	SP0923	This distribution: SP1023
Sy.x	11.17	1.98	2.83	5.78	0.44	6.06
IS	7	0	1	2	0	2

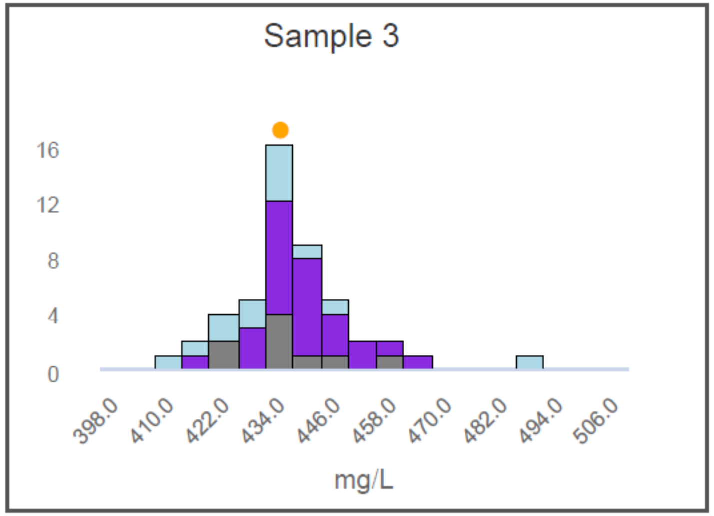


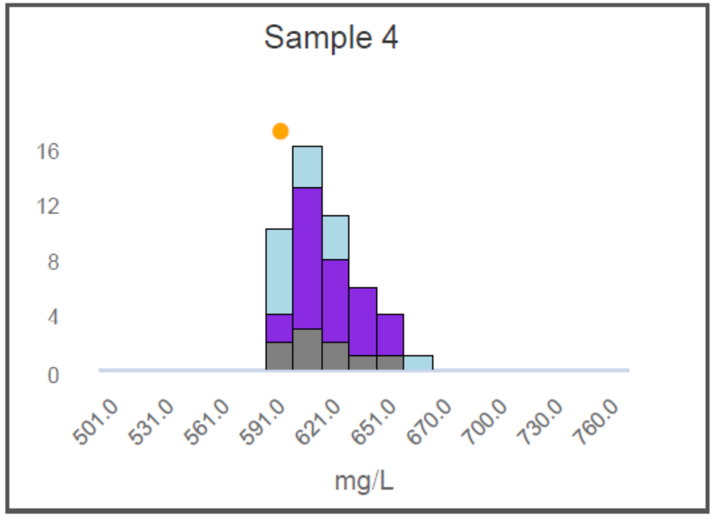
Sy.x is the average deviation from the best fit line and is an index of scatter.

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

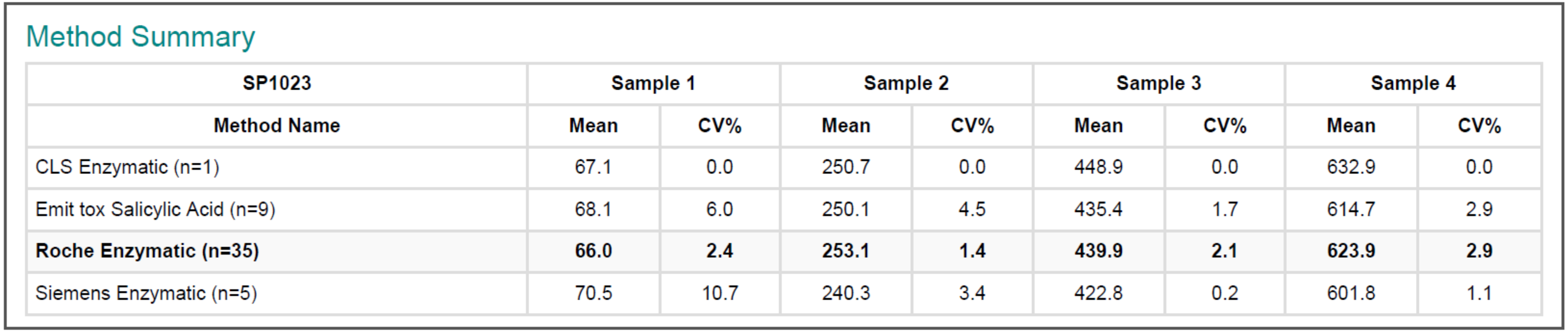








■ All Results ■ My Method ■ My Instrument ● My Result



Method Summary

SP1023	Sample 1		Sample 2		Sample 3		Sample 4	
Method Name	**Mean**	**CV%**	**Mean**	**CV%**	**Mean**	**CV%**	**Mean**	**CV%**
CLS Enzymatic (n=1)	67.1	0.0	250.7	0.0	448.9	0.0	632.9	0.0
Emit tox Salicylic Acid (n=9)	68.1	6.0	250.1	4.5	435.4	1.7	614.7	2.9
Roche Enzymatic (n=35)	**66.0**	**2.4**	**253.1**	**1.4**	**439.9**	**2.1**	**623.9**	**2.9**
Siemens Enzymatic (n=5)	70.5	10.7	240.3	3.4	422.8	0.2	601.8	1.1

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

Instrument Report

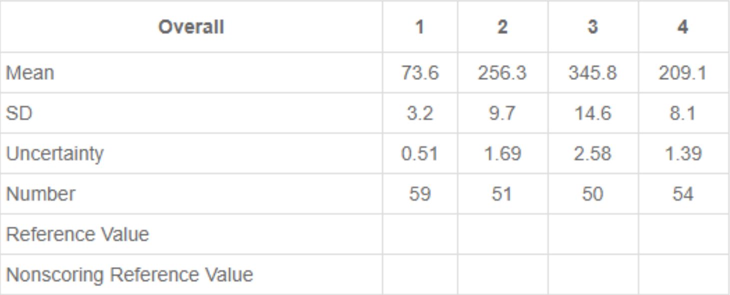
Distribution Code: **SP0823**
Distribution Date: **07-Aug-2023**
Analyte: **Paracetamol (mg/L)**
Method: **All**
Manufacturer: **All**
Instrument Model: **All**
Kit: **All**

Paracetamol

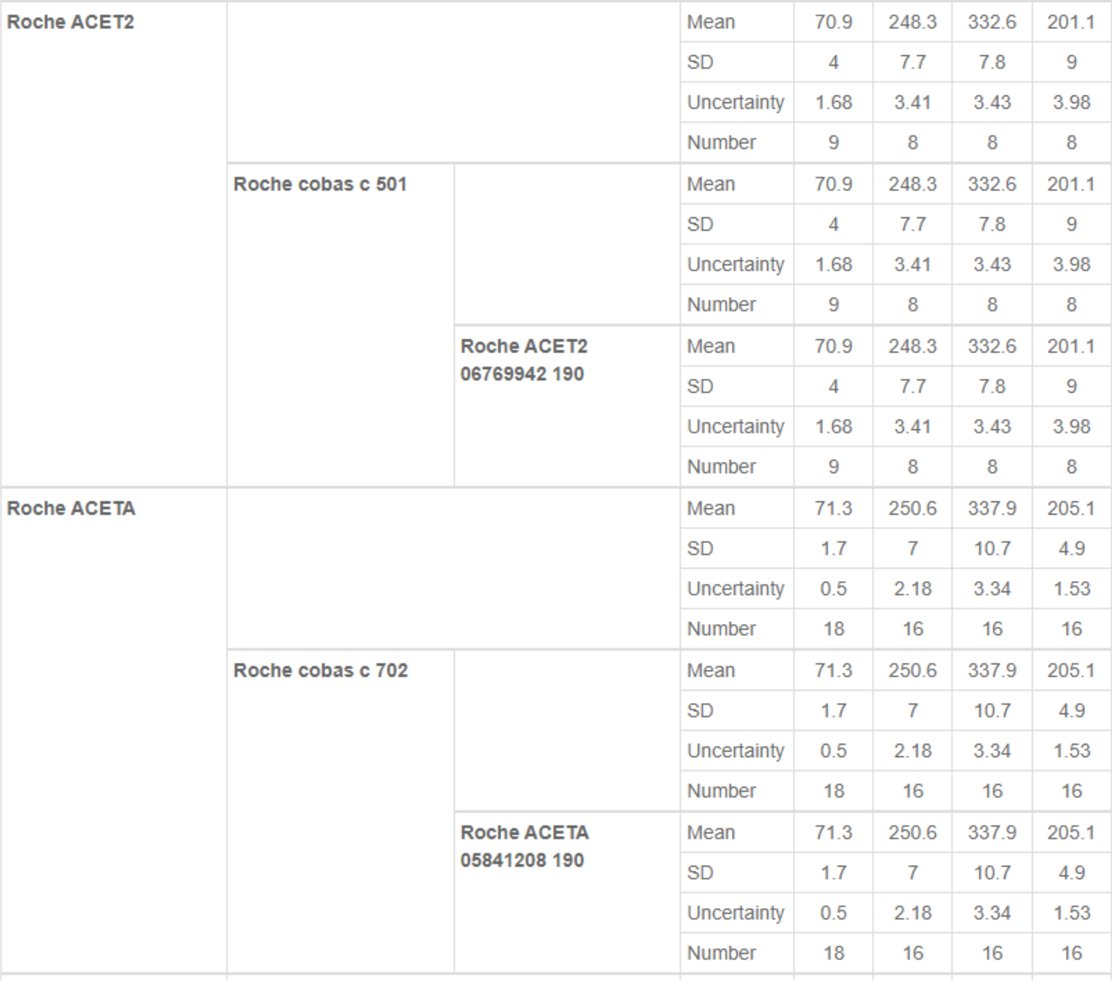
Key

red	Outside Expected Range
*	Method Transformed

Participant Code	1	2	3	4
WQ00001				
WQ00008	74.16	269.05	365.54	218.84
WQ00008	76.53	271.75 *	367.98 *	220.1
WQ00009	71	252	341	207
WQ00009	73	270	365	219
WQ00013				
WQ00013	72.6	247.3	328.7	204.3
WQ00019	74	260	349	210
WQ00019	73	258	348	209



Overall	1	2	3	4
Mean	73.6	256.3	345.8	209.1
SD	3.2	9.7	14.6	8.1
Uncertainty	0.51	1.69	2.58	1.39
Number	59	51	50	54
Reference Value				
Nonscoring Reference Value				



Roche ACET2			Mean	70.9	248.3	332.6	201.1
			SD	4	7.7	7.8	9
			Uncertainty	1.68	3.41	3.43	3.98
			Number	9	8	8	8
	Roche cobas c 501		Mean	70.9	248.3	332.6	201.1
			SD	4	7.7	7.8	9
			Uncertainty	1.68	3.41	3.43	3.98
			Number	9	8	8	8
		Roche ACET2 06769942 190	Mean	70.9	248.3	332.6	201.1
			SD	4	7.7	7.8	9
			Uncertainty	1.68	3.41	3.43	3.98
			Number	9	8	8	8
Roche ACETA			Mean	71.3	250.6	337.9	205.1
			SD	1.7	7	10.7	4.9
			Uncertainty	0.5	2.18	3.34	1.53
			Number	18	16	16	16
	Roche cobas c 702		Mean	71.3	250.6	337.9	205.1
			SD	1.7	7	10.7	4.9
			Uncertainty	0.5	2.18	3.34	1.53
			Number	18	16	16	16
		Roche ACETA 05841208 190	Mean	71.3	250.6	337.9	205.1
			SD	1.7	7	10.7	4.9
			Uncertainty	0.5	2.18	3.34	1.53
			Number	18	16	16	16