

Weqas
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Llanishen, Cardiff, CF14 5DU

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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

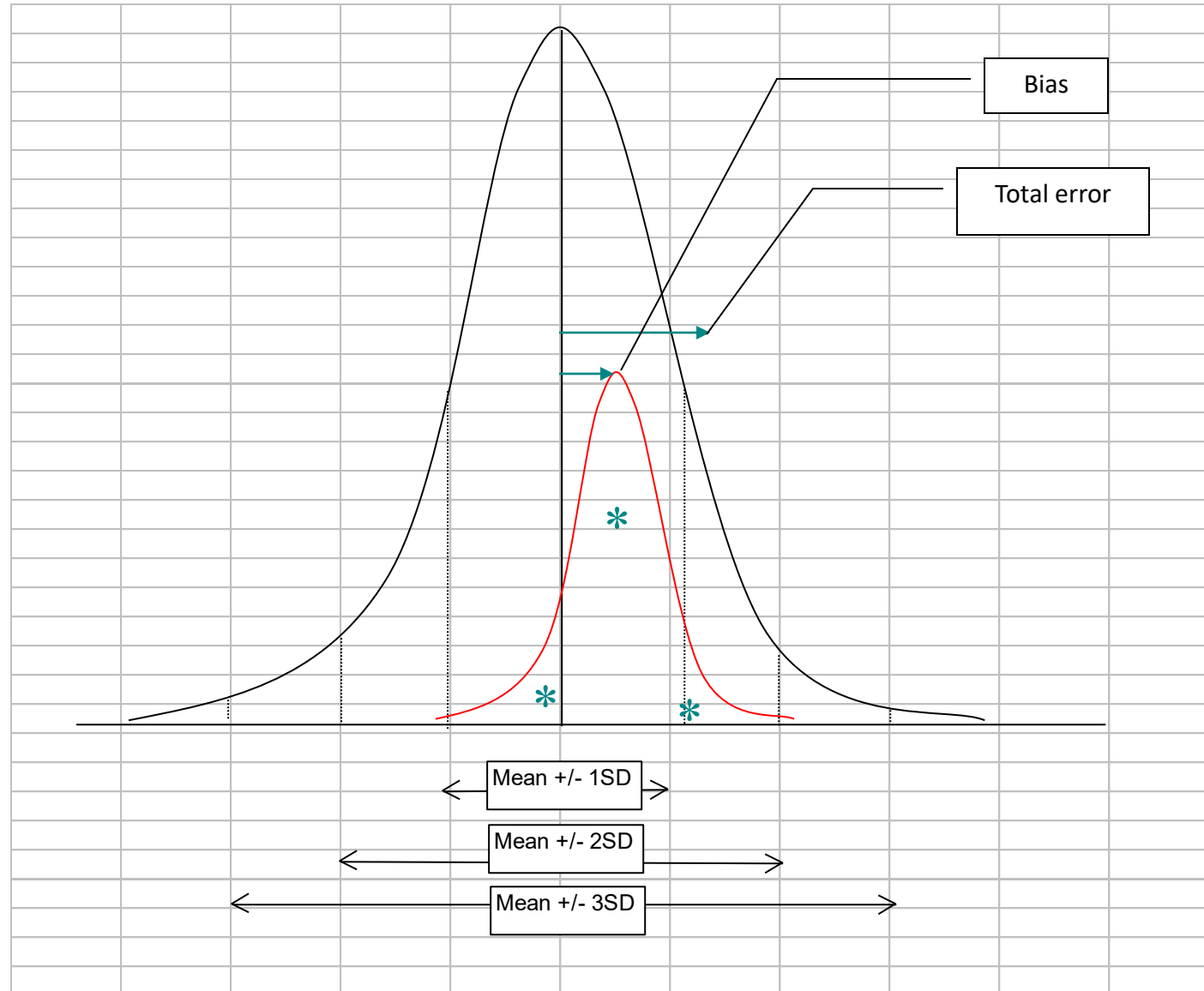
Identifies components of both Imprecision and Inaccuracy

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

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

where

y = observed value

$\bar{y}$ = expected value

d.f. = degrees of freedom

Standard dev of residuals

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

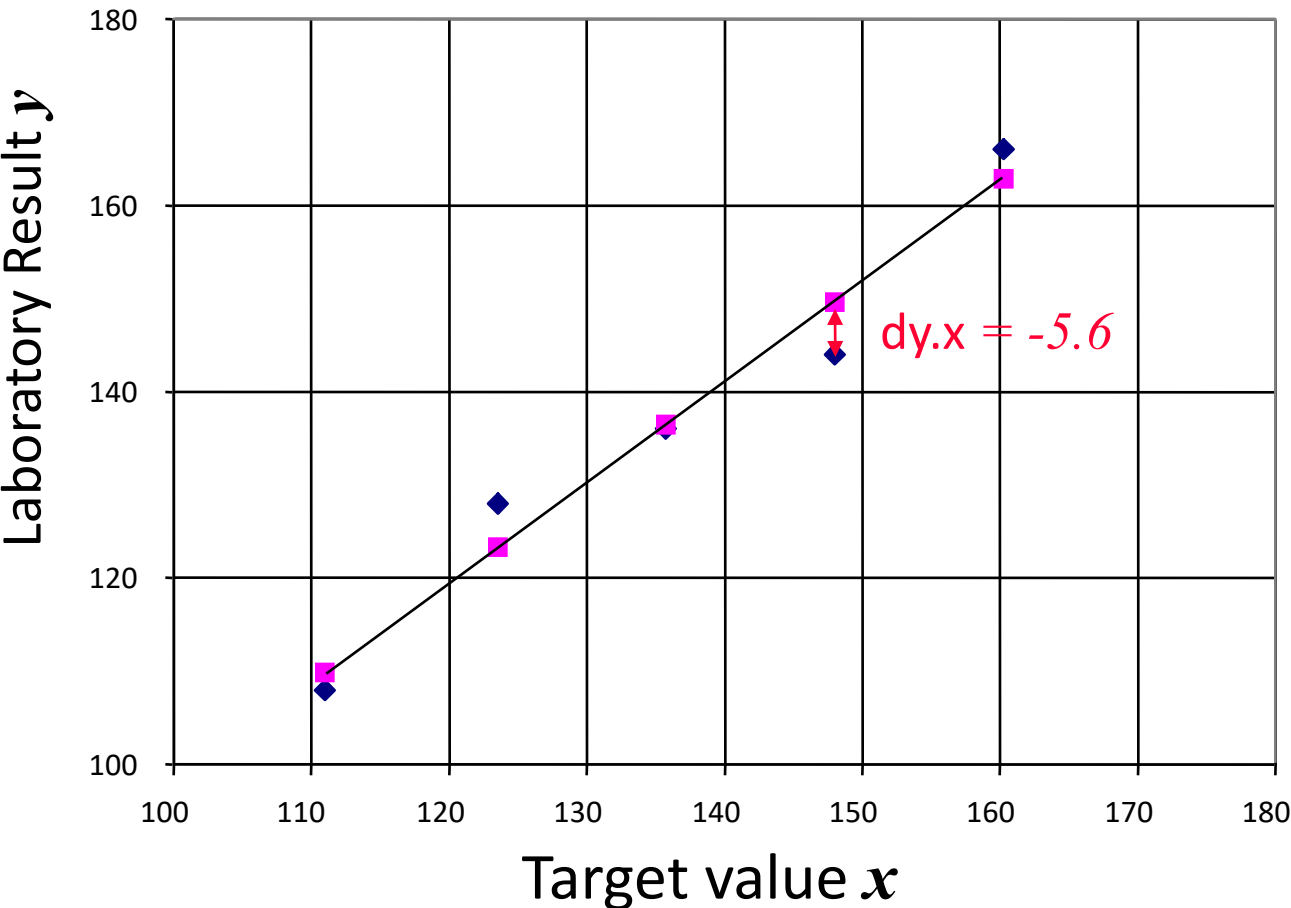
where

$\tilde{y}$ = 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

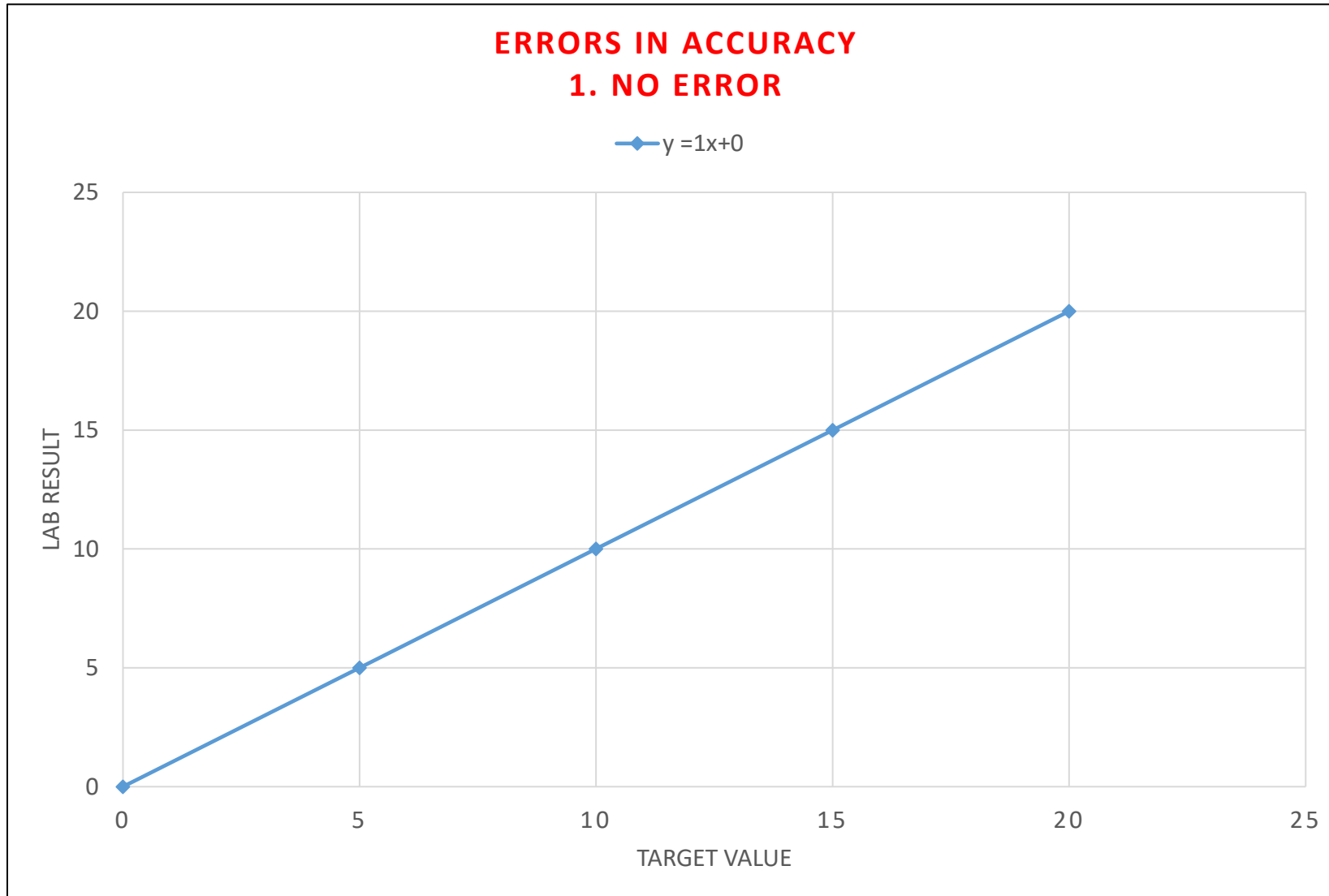
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Interpretation of Inaccuracy

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.

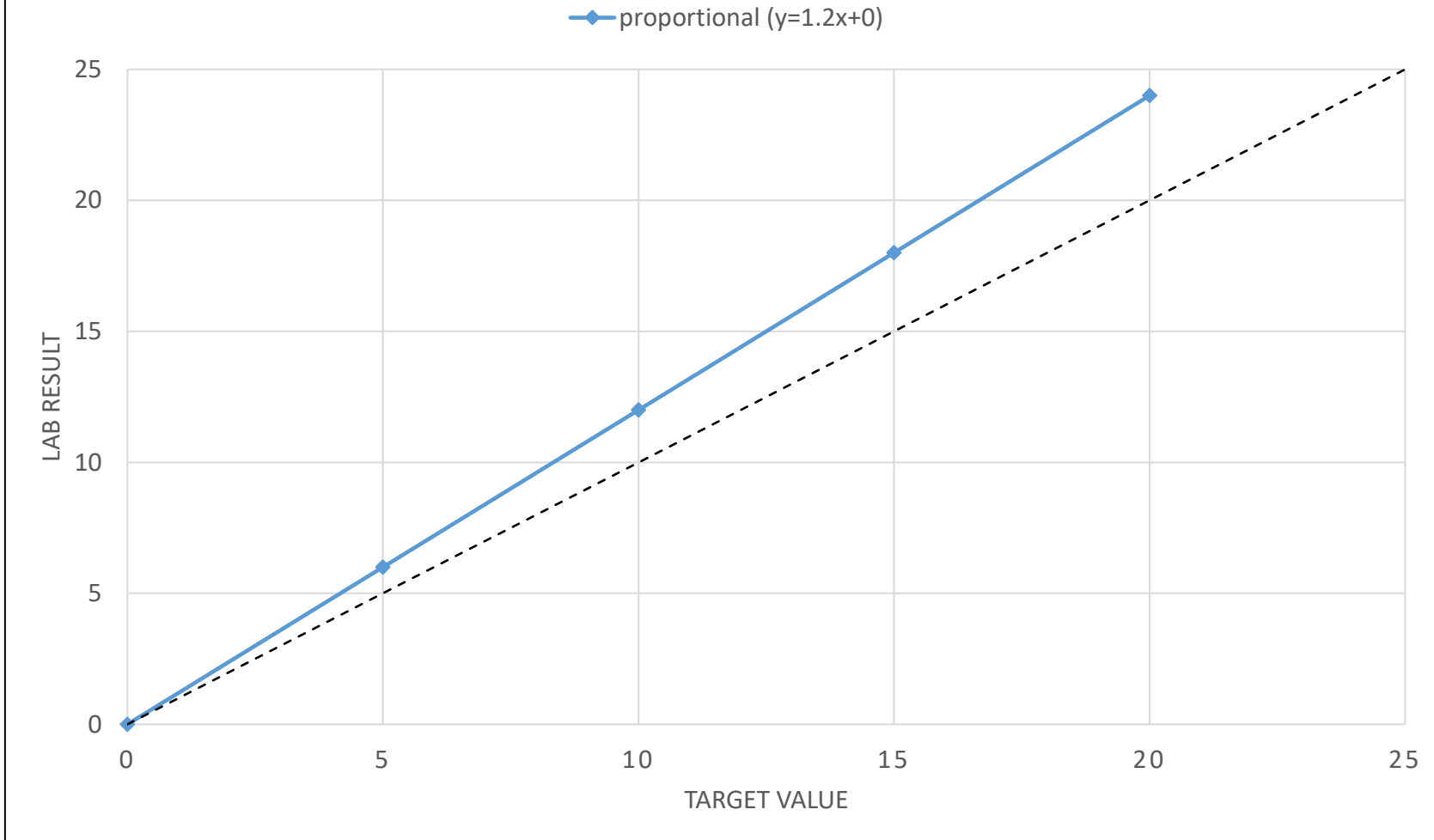
$$y = mx + c$$

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



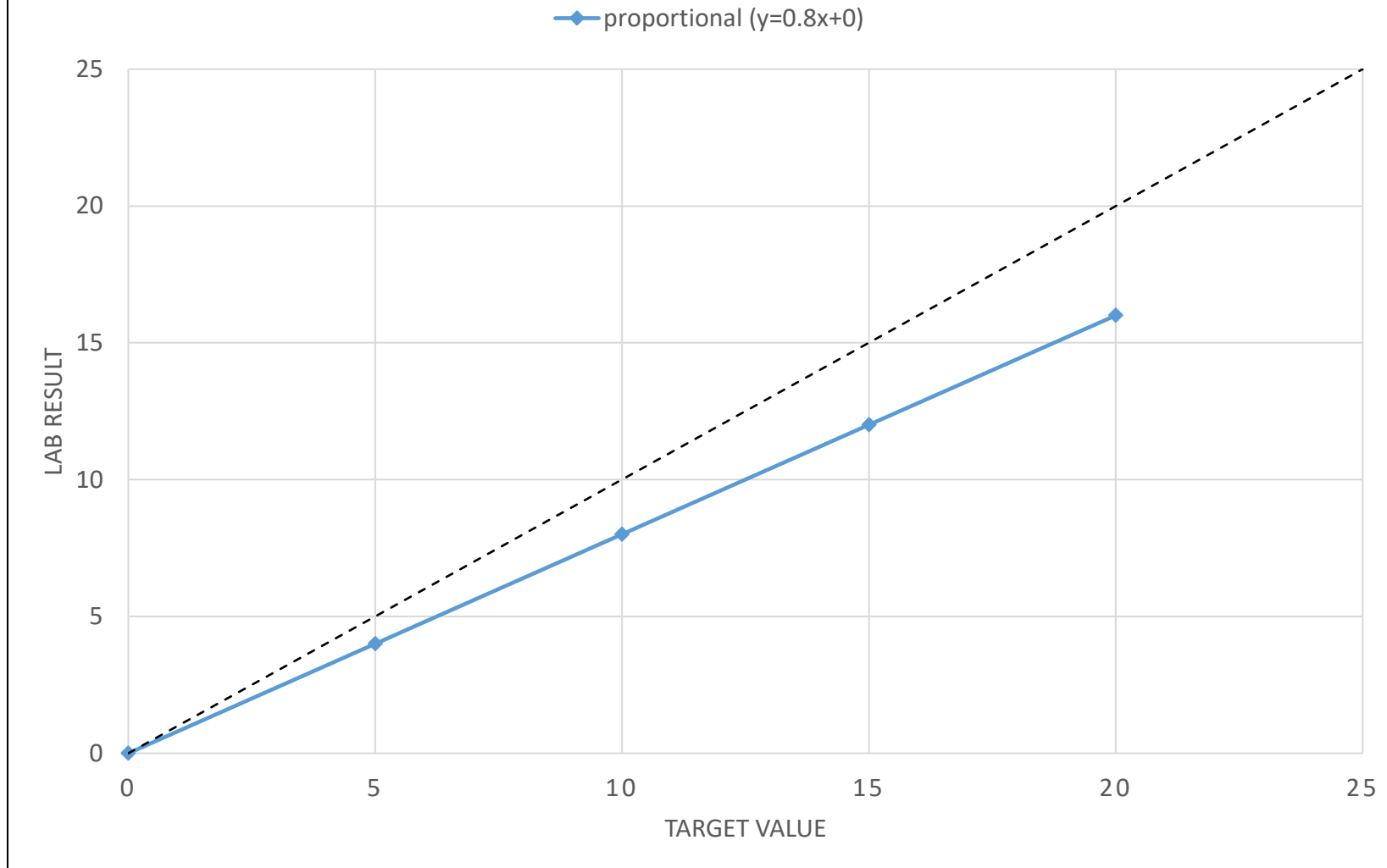
ERRORS IN ACCURACY

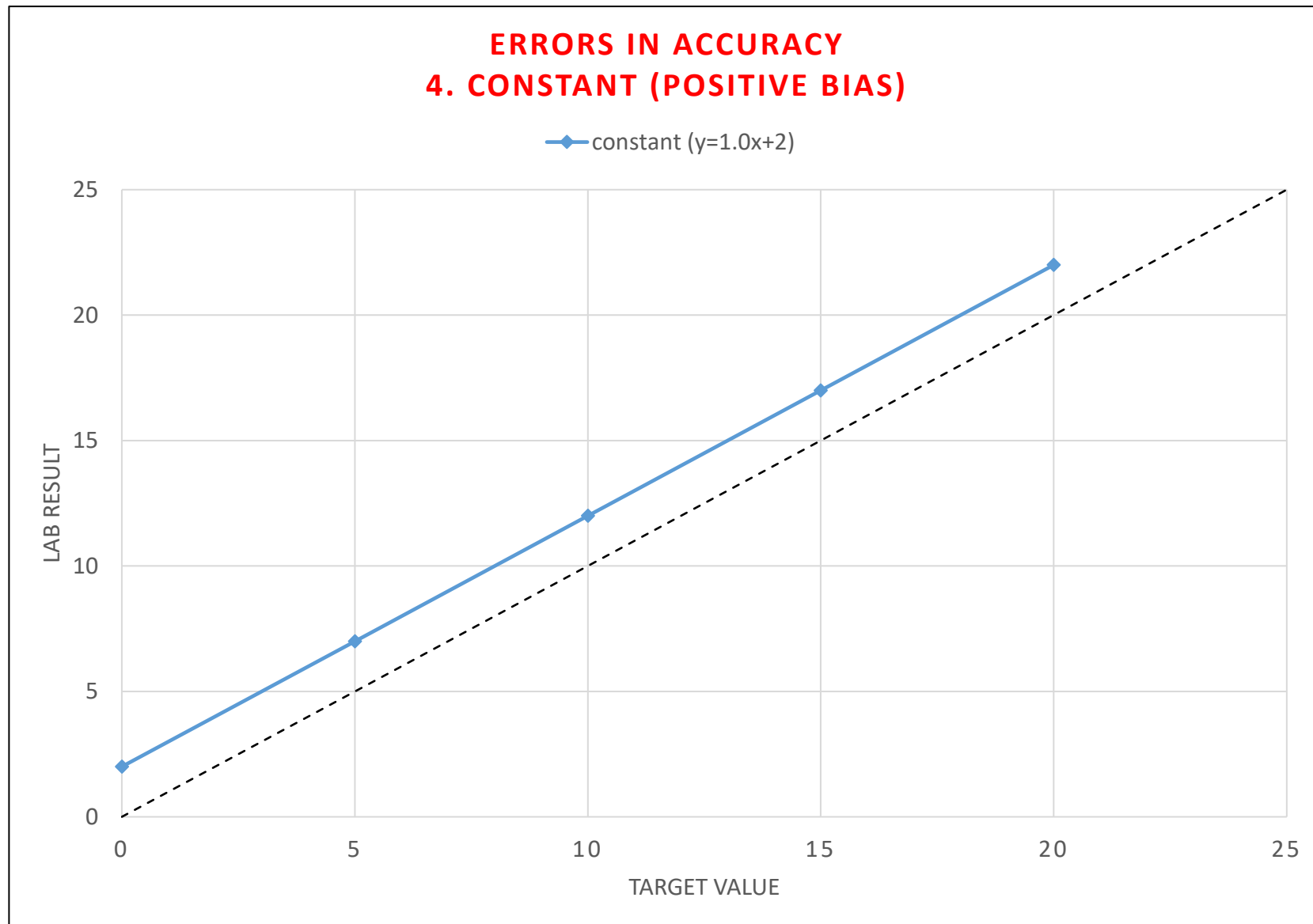
2. SYSTEMATIC PROPORTIONAL (POSITIVE BIAS)



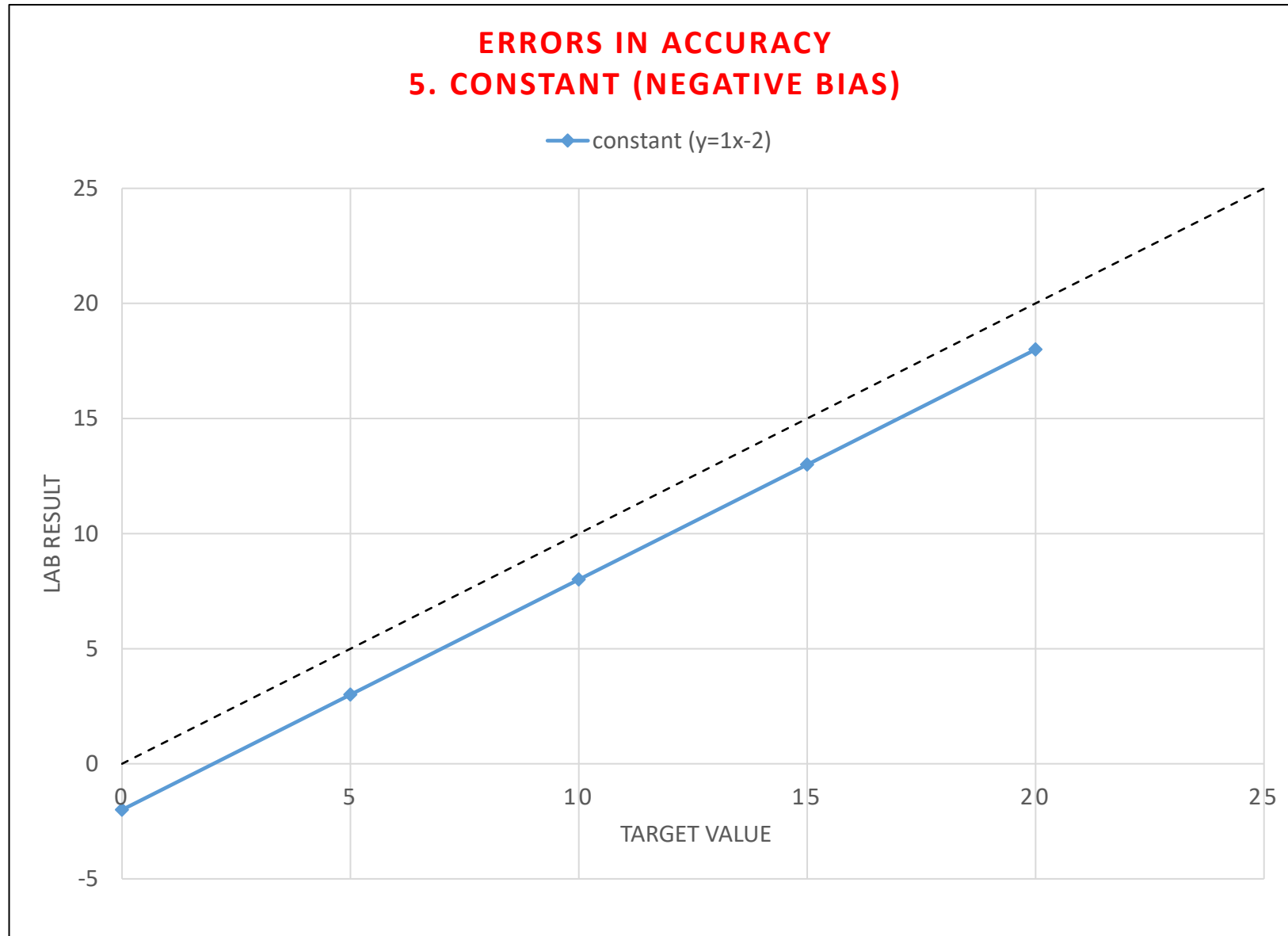
ERRORS IN ACCURACY

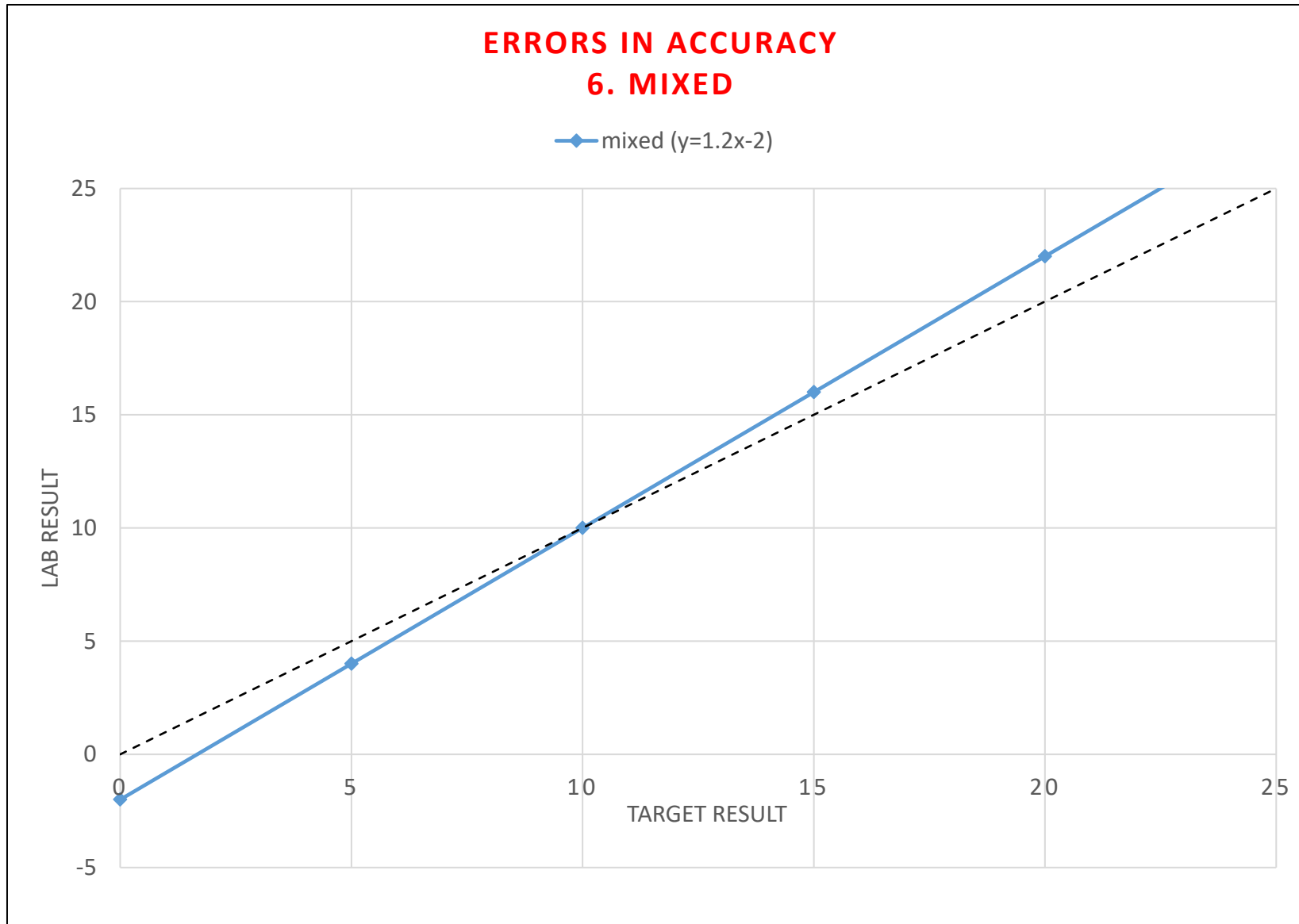
3. SYSTEMATIC PROPORTIONAL (NEGATIVE BIAS)

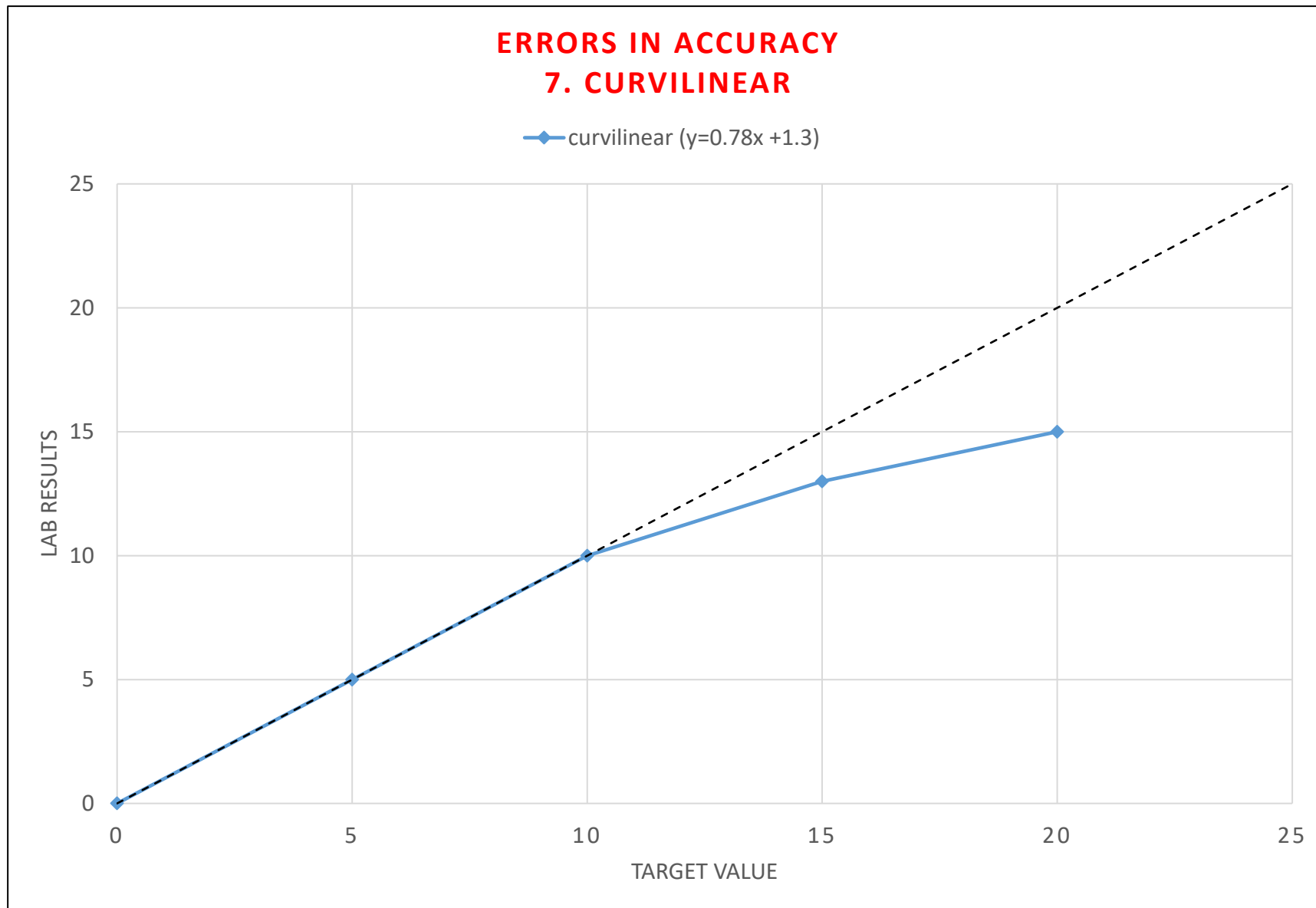


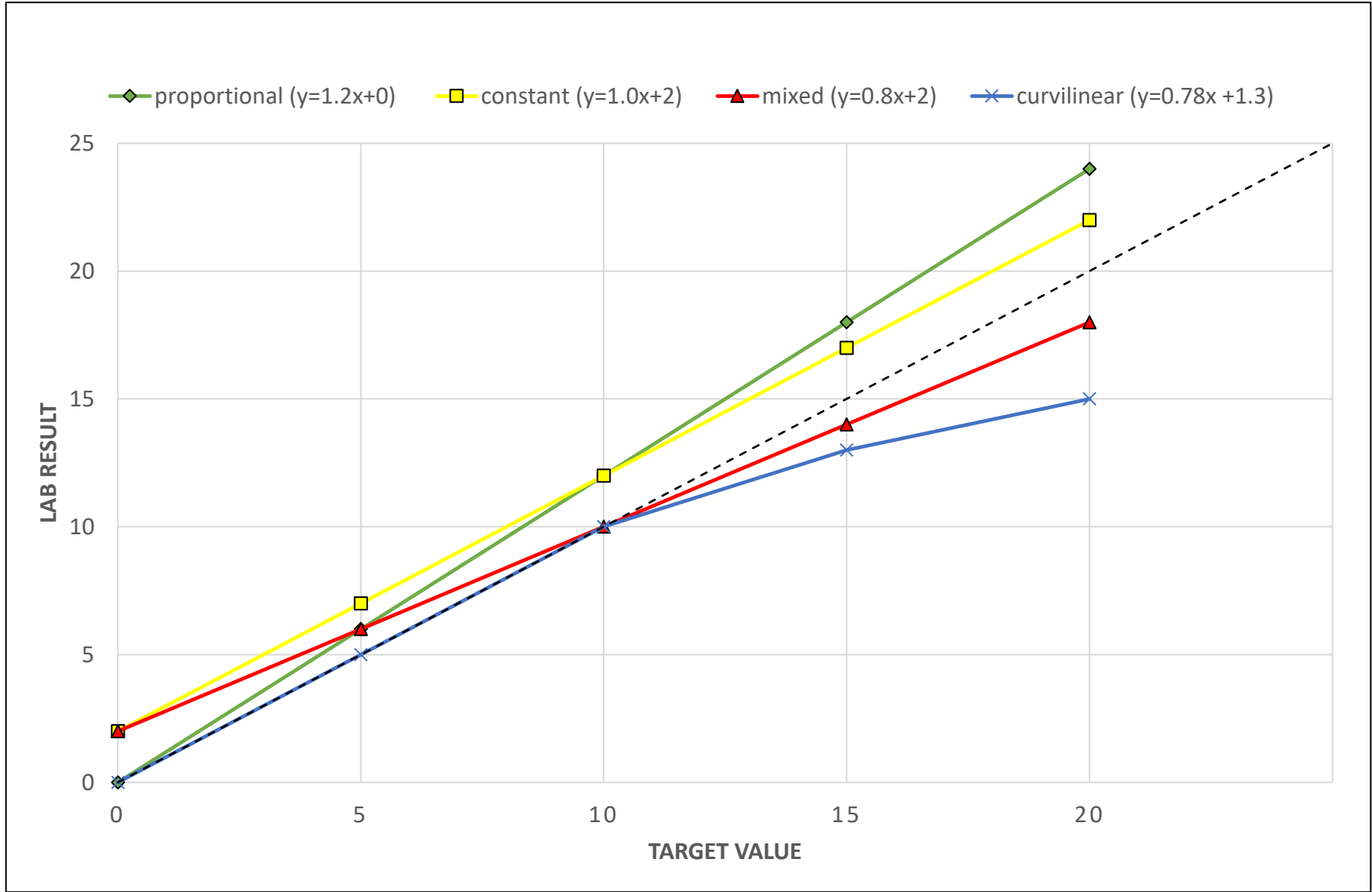


ERRORS IN ACCURACY 5. CONSTANT (NEGATIVE BIAS)









	Imprecision		Inaccuracy		
	Random	Curvilinear	Prop	Mixed	Constant
Slope	No	Yes/No	Yes	Yes	No
Intercept	No	Yes/No	No	Yes	Yes
$S_{y,x}$	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 $n \geq 8$

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

Instrument mean – on report for information only

Reference Target Values

Generation of Reference Target Values

- Specialist Laboratories Required
- Accredited to ISO17025 (in accordance with ISO15195)
- Limited number of laboratories worldwide

Advantages 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

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

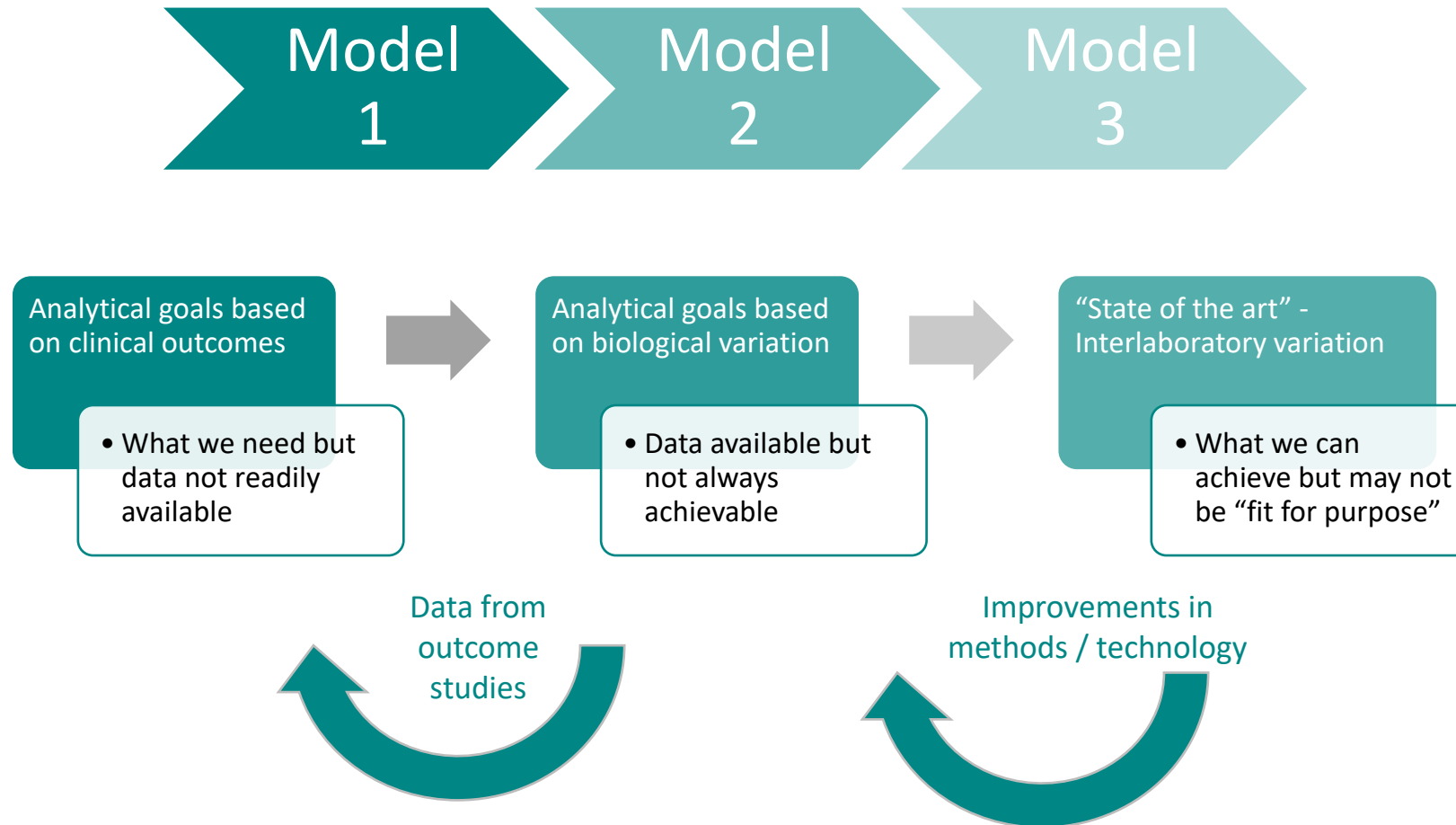
- Testosterone
- Cortisol

IDGC-MS

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

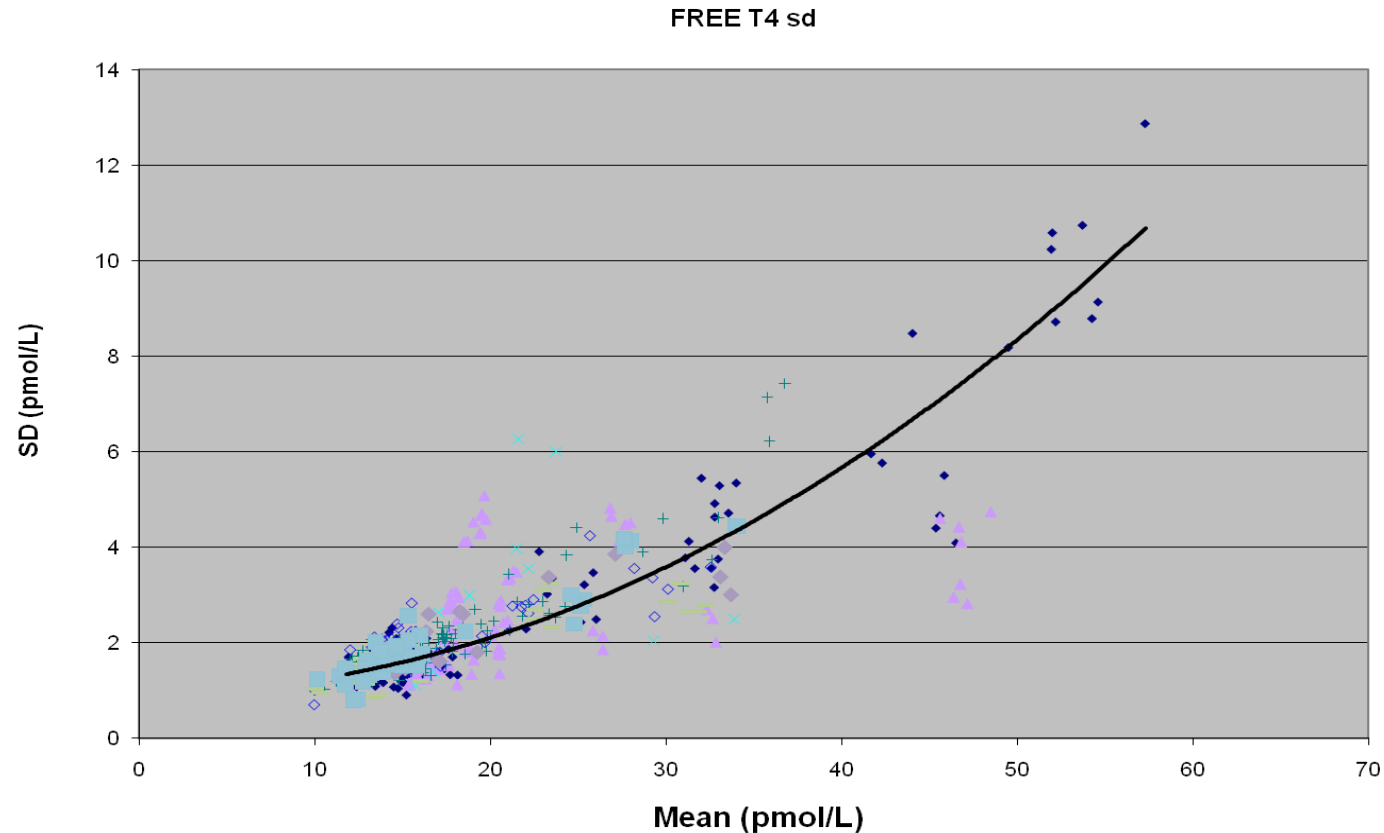
Analytical Performance Specifications (APS)

Analytical Performance Specifications (APS)



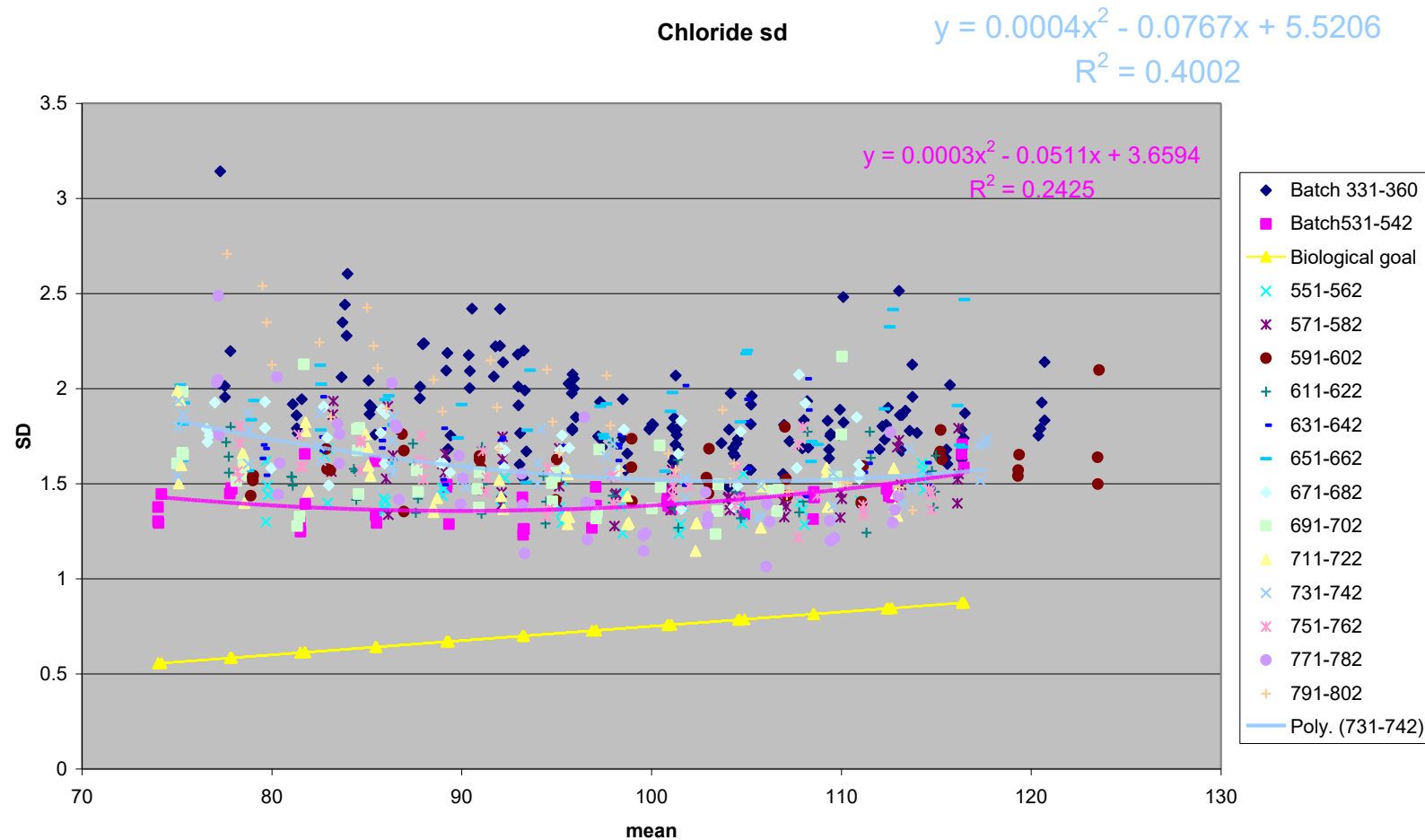
Interlaboratory variation (state of the art)

FT4



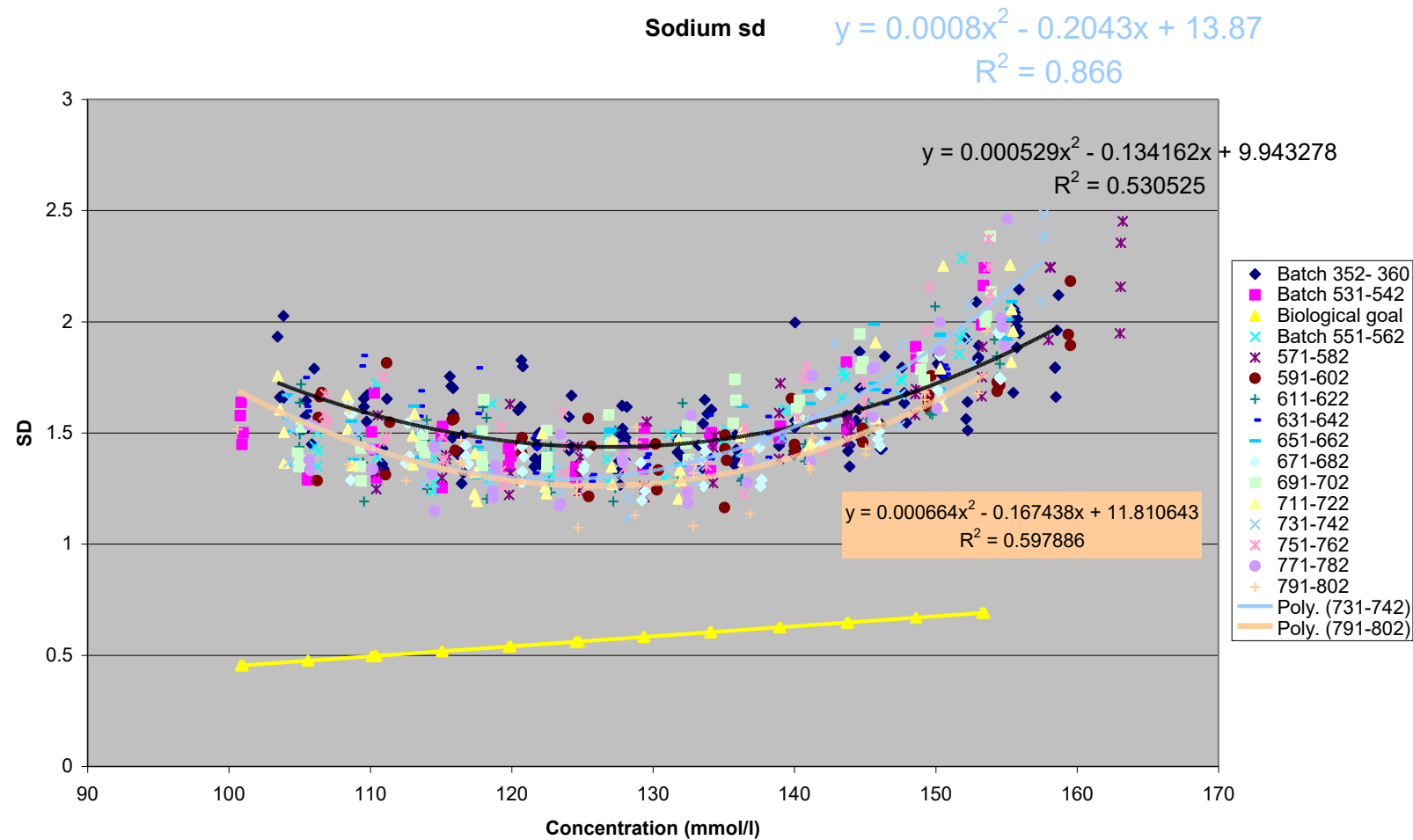
Relationship of analyte conc. to SD follows a polynomial equation for most analytes
and is non linear therefore using fixed % TE is not appropriate

“State of the art” v Biology



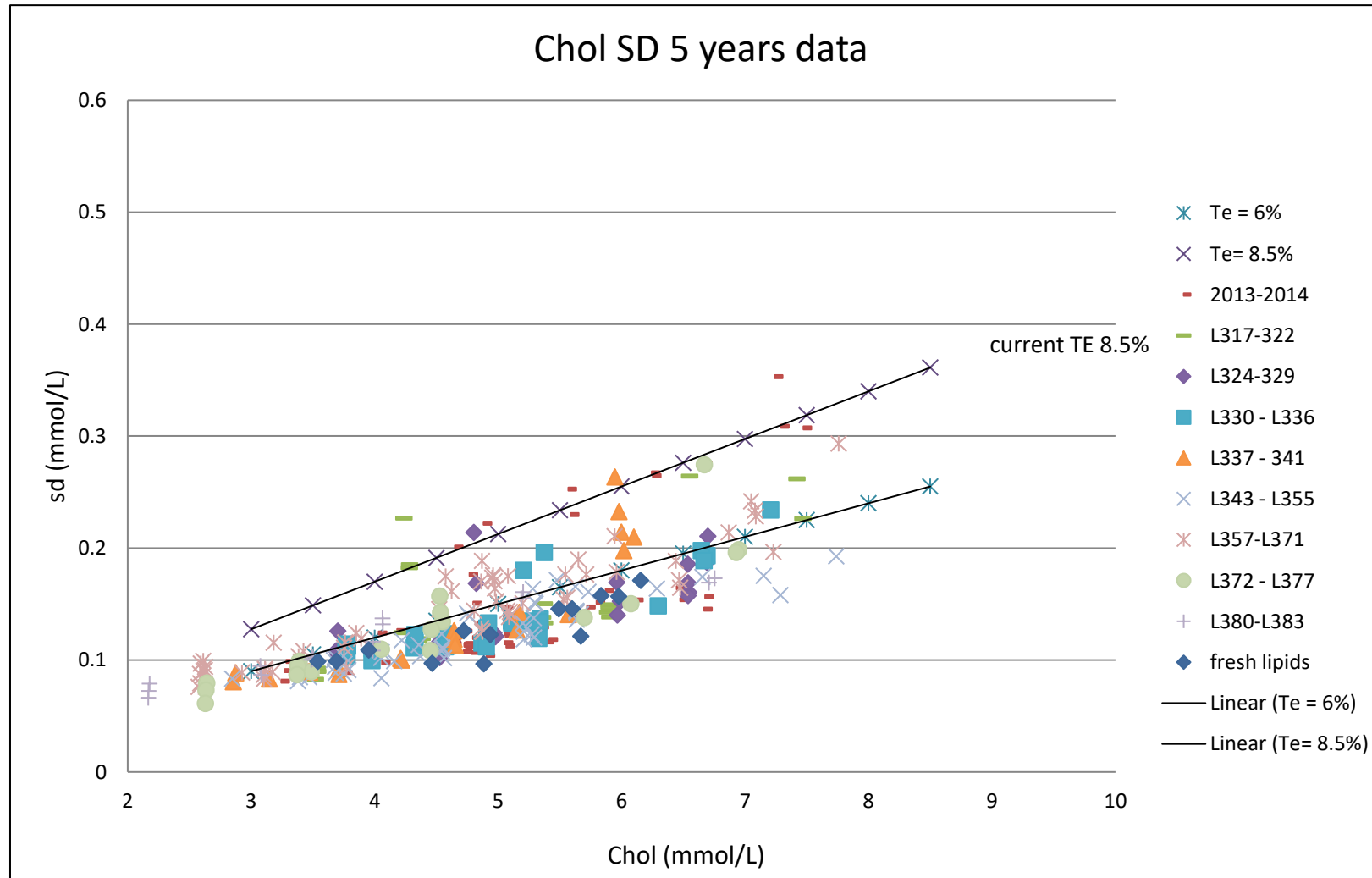
Biological goals not achievable. Performance has not improved over time.

“State of the art” v Biology



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

“State of the art” v Biology



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Weqas Connect Reports

Standard Quantitative Report

Participant Code: WQ00000

#####

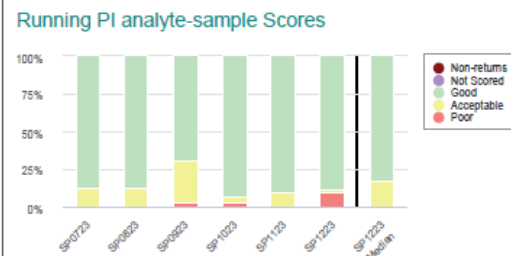
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Programme Organiser: Mrs Annette Thomas

Weqas

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%
97.5 th Centile % Poor PI	40%



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
replaces Lab Code.

Participant Code: WQ00000

#####

Your % Poor PI
(Performance Index)
across all samples for all
instruments, the Median
All Participants % Poor
PI and the 97.5th Centile
% Poor PI.

Distribution details
and report status.

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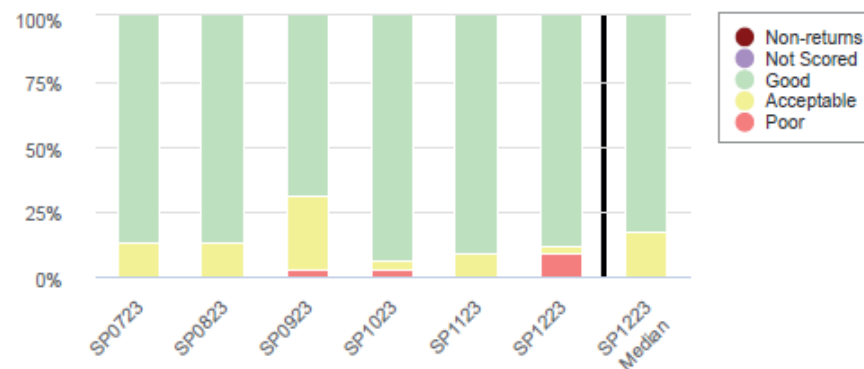
Programme Organiser: Mrs Annette Thomas

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%
97.5 th Centile % Poor PI	40%

Running PI analyte-sample Scores



PI Ranges

<1	Good
1-2	Acceptable
>2	Poor

The running table
shows the current
distribution PI scores,
and ultimately the
previous 5 distribution
PI scores for all
analytes, for your
Participant Code, plus
all-Participant Median
performance.

The PI Scores table shows performance for all analytes and all instruments.

Overall % Poor PI across all analytes for each instrument, and Overall % non return for each instrument.

Key for PI Codes.

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 scores are converted into performance categories and colour coded.

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.

Distribution Specific Comments from Weqas or participant.

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

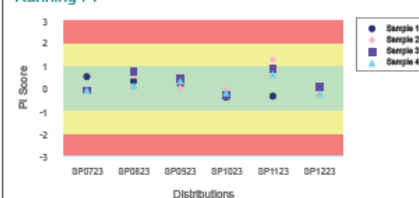
Analyte: Salicylate - Method: Roche Enzymatic - Kit: SALI

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

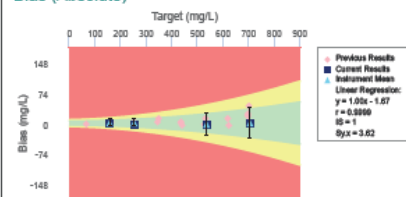
Scoring

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

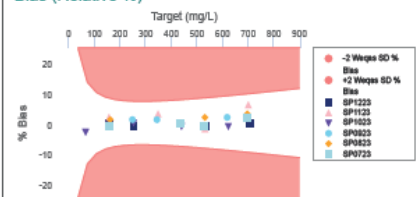
Running PI



Bias (Absolute)



Bias (Relative %)

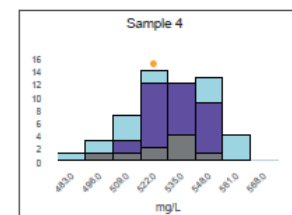
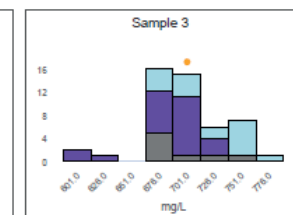
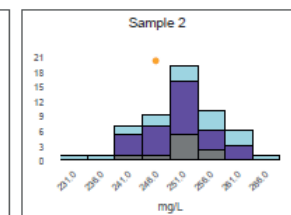
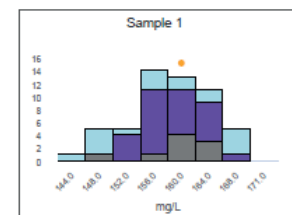


Precision

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

Syx 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

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.

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 • **Analysers 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

‘Your reported result’ will be shown in the units entered, in the Weqas standard units if units entered are different from the Weqas standard units, and method corrected (if appropriate for the analyte).

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

Target Value: This will show whether you have been scored against Reference Value, Method Mean or Overall Mean.

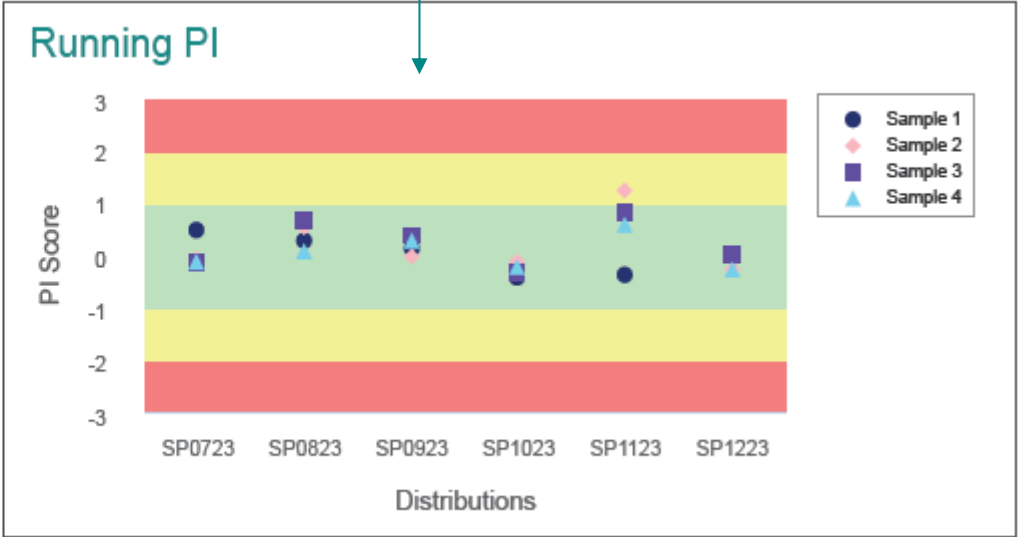
Weqas TAE: This is the Total Allowable Error (2 x Weqas SD).

PI (Performance Index) score is shown for each sample.

$$PI = \frac{\text{Reported Result} - \text{Target Value}}{(\text{Weqas TAE} / 2)}$$

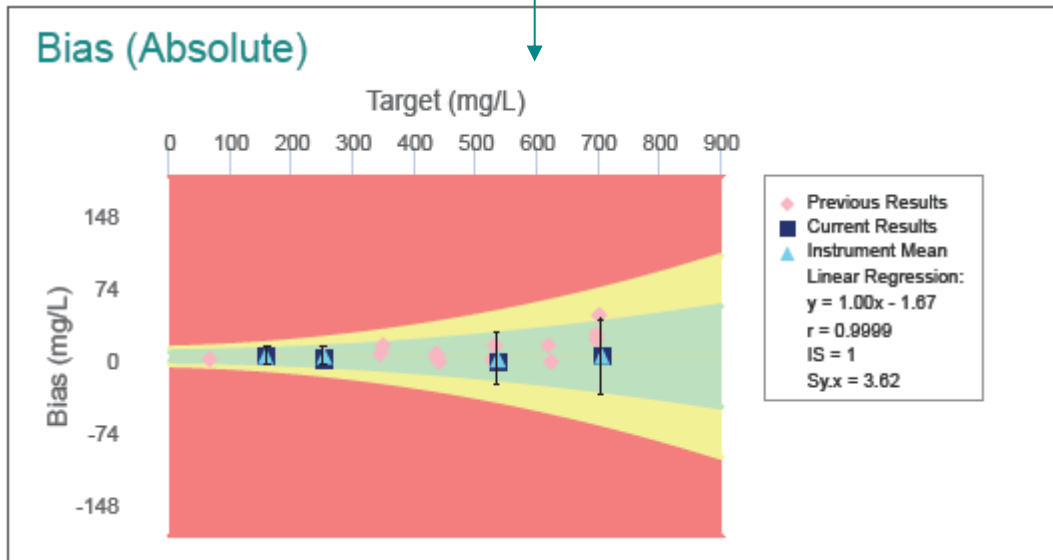
Overall performance category is assigned using an algorithm based on the individual sample PIs.

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

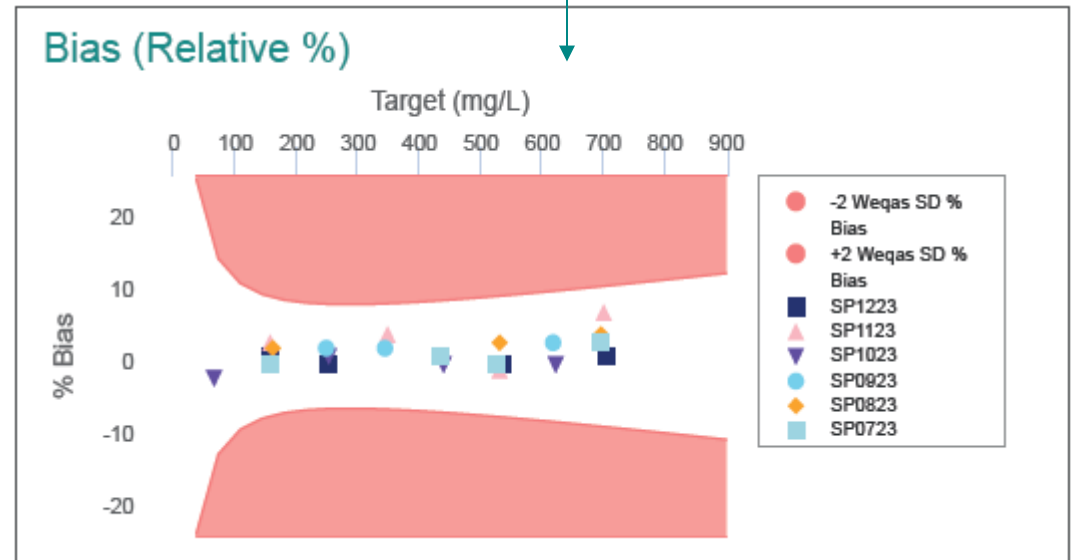


Running PI chart shows the PI score for each sample for the current distribution and the last 5 distributions, with colour coding for each performance category.

The Bias (Absolute) Plot shows absolute bias in Weqas standard units for each sample for the current distribution. The x-axis is the target value; if the target value is a Reference Value or the Overall Mean, your Method Means will be plotted.



The Bias (Relative) Plot show the relative (%) bias to the target for the current results, and for the previous 5 distributions.



Precision

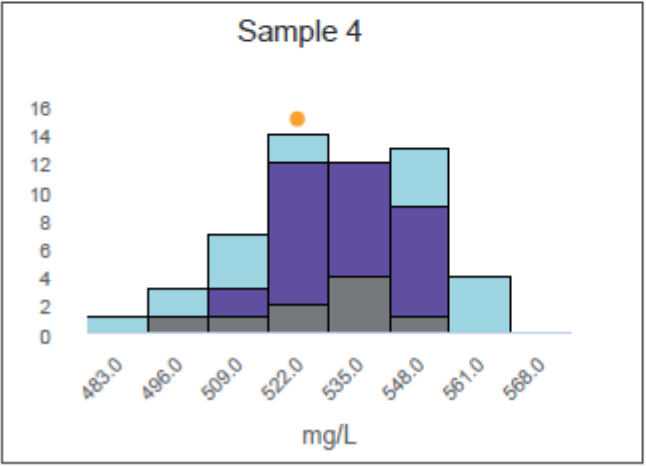
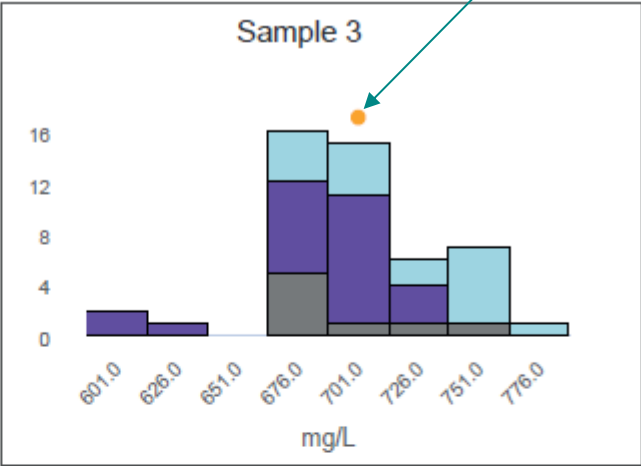
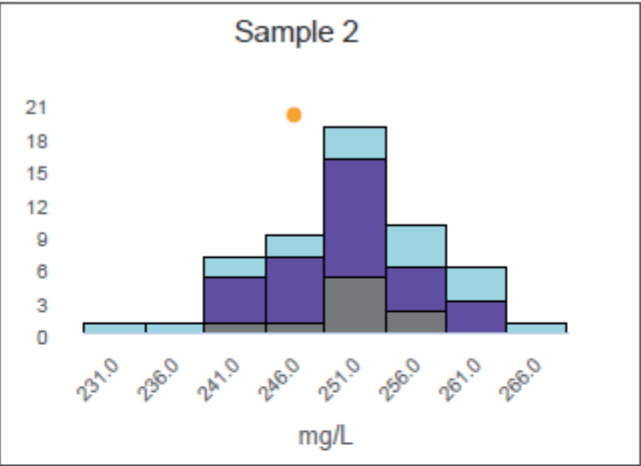
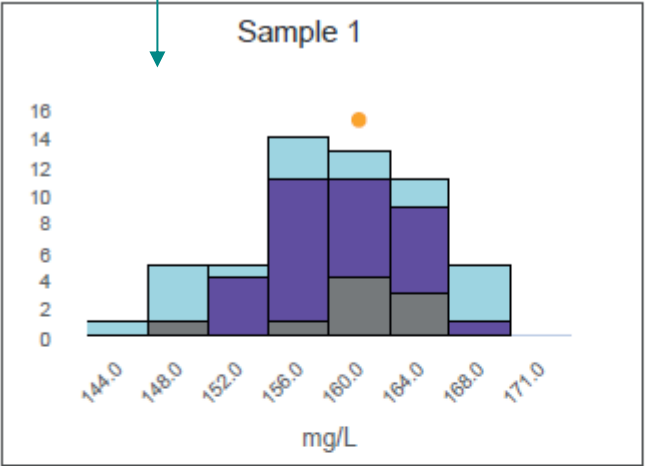
	SP0723	SP0823	SP0923	SP1023	SP1123	This distribution: SP1223
Sy.x	8.28	6.26	2.05	1.72	22.32	3.62
IS	4	2	0	0	27	1

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)

The histogram shows breakdown of results for each sample, showing the spread of results for All Results, 'My Method' and 'My Instrument'.

The orange dot shows where your result lies.



The Method Summary shows Mean and CV for each Method for each sample.

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.

Any analyte specific comments from Weqas or the participant are shown here.

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 ($2 < PI \leq 3$)
		(number of samples in distribution > 1) and (2 or more $ PI > 2$) (<i>Westgard 2_{2s}</i>)
		(number of samples in distribution > 1) AND (sign $x_i \neq \text{sign } x_j$) AND $ x_i > 2$ AND $ x_j > 2$ * for at least one pair of scores x_i and x_j where x_n with $i \neq j$ are the individual sample-analyte scores for the instrument in question (<i>Westgard R_{4s}</i>)
Orange	Warning	(number of samples in distribution > 1) and (single sample with $2 < PI \leq 3$) and (no sample with $ PI > 3$)
Yellow	Acceptable	(any number of samples in distribution) AND ($1 < \text{Max } PI \leq 2$)
Green	Good	$ PI < 1$ for all samples Green is only assigned if all the individual samples are good.

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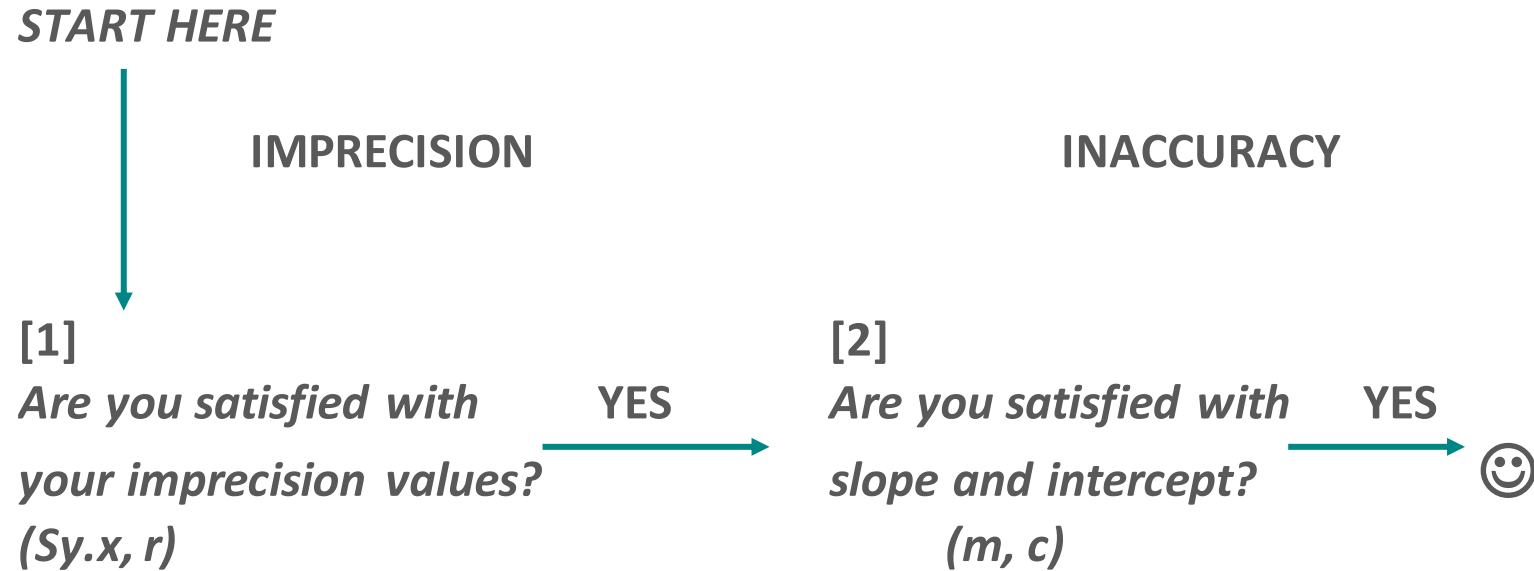
REFERENCE
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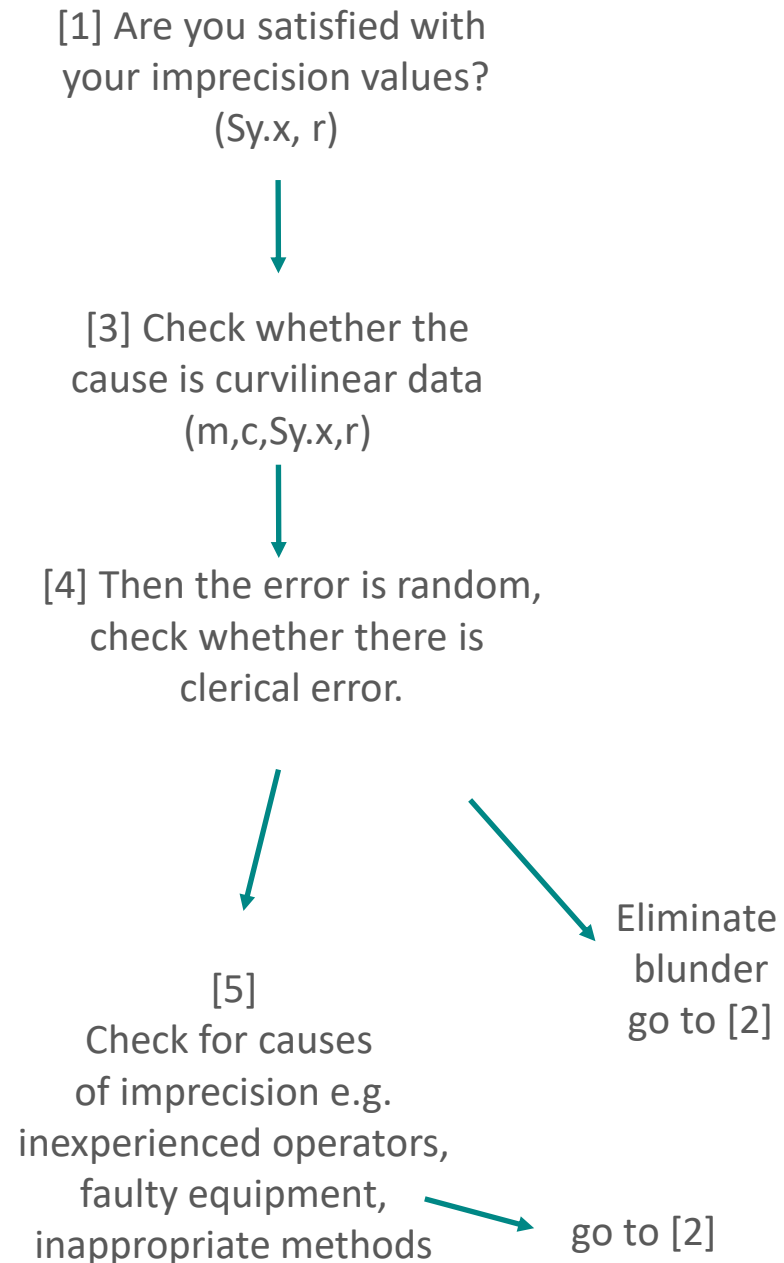


EDUCATION &
TRAINING

Problem Solving and Cases

Problem Solving Flow Chart



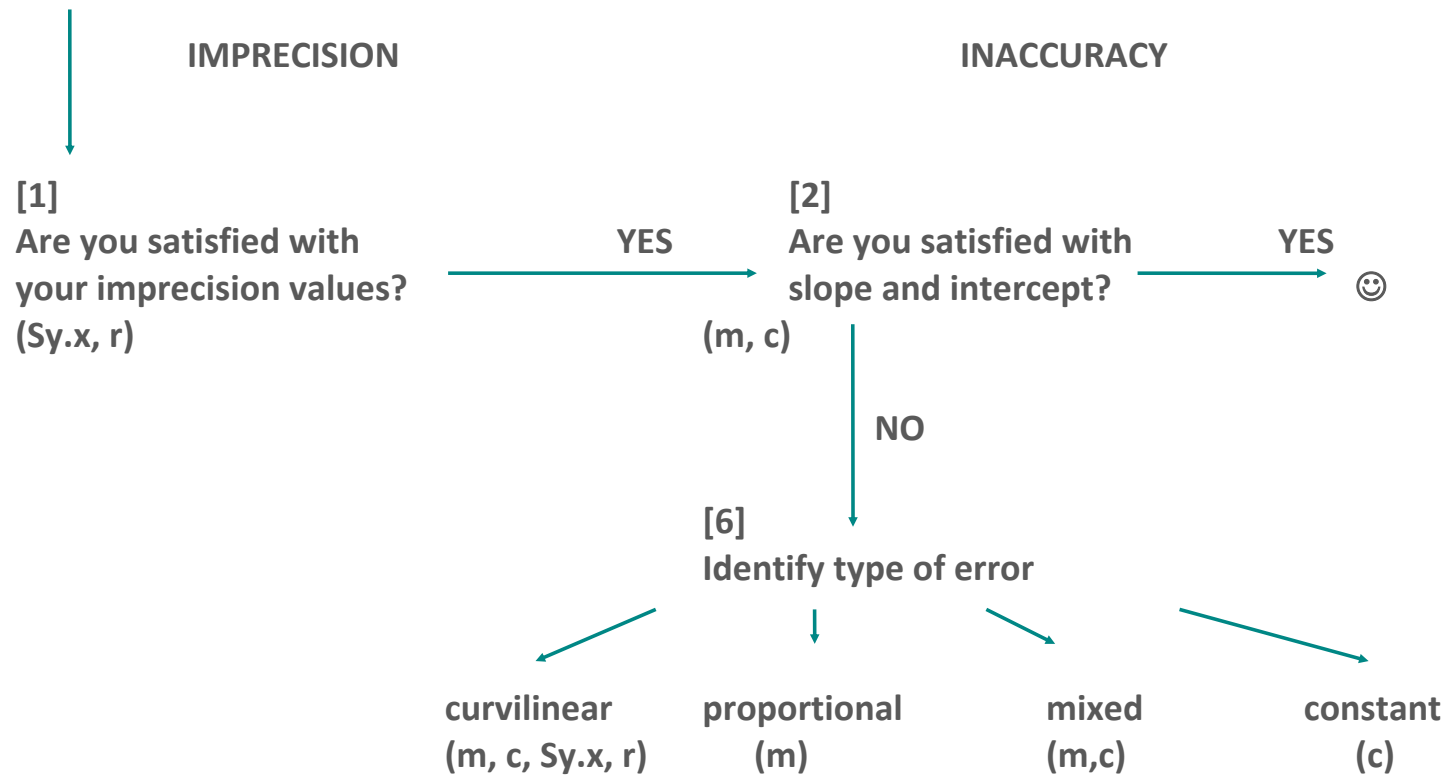


Problem Solving Flow Chart

IMPRECISION

Problem Solving Flow Chart

START HERE



Problem Solving Flow Chart

INACCURACY

