Weqas

GLOBAL PROVIDER OF QUALITY
IN DIAGNOSTIC MEDICINE

INTERPRETATION OF EQA REPORTS - INTERACTIVE (weqas.com)

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Contents

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1. Statistical Analysis - Quantitative Programmes

THIS DOCUMENT APPLIES TO ALL LABORATORY AND POCT PROGRAMMES LISTED IN THE FOLLOWING TABLES. QUALITATIVE PROGRAMMES ARE COVERED IN SECTION 2.

A separate Report Interpretation Guide (Reference PD-GD-1) is available for programmes managed through the Weqas Connect EQA portal.

The linear panel of samples used in most Weqas Programmes allow the evaluation of ***inaccuracy, within run imprecision and between batch imprecision.***

Table 1 - Laboratory Programmes

Weqas Programme Title	Additional Sub Programmes / Comments
Serum Chemistry	Serum Indices interference studies
HIL Serum Indices	
Serum hCG	Qualitative and Quantitative Serum hCG
Porphyrin	Includes Quantitative and Qualitative Urine, plasma, faeces and clinical cases
TDM	
Drugs of Abuse	
Pre-Eclampsia	

Table 2 - POCT Programmes

Weqas Programme Title	Additional Sub Programmes / Comments
Pregnancy Testing	Qualitative Urine and Serum Programmes
POCT HIV	
Pre Term Labour Markers	Fetal fibronectin. Phosphorylated IGFBP-1. POCT PROM.
Drugs of Abuse	Offered with simplified reports in Lab Programme
POCT D-Dimer	
Viscoelastic Haemostasis^{+}	
POCT Respiratory Virus^{+}	
POCT Strep A^{+}	

$^{+}$ Pilot (Not Accredited)

1.1 Target value assignment and Traceability

Statistical methods that are robust to outliers complying in accordance with/of *ISO 13528:2015: Statistical methods for use in proficiency testing by interlaboratory comparison* are used. For each analyte for each sample the overall Robust mean and standard deviation is calculated using Algorithm A with iterated scale.

Methods are grouped into broad method groups based on the principle of the method, e.g. Glucose Method 1 = Glucose Oxidase, Method 2 = Hexokinase as well as the platform (analyser) type. The Robust method mean and analyser mean are calculated using Algorithm A as above. Each laboratory's results are compared against target values using linear regression analysis to give a measure of systematic error. The target value can either be:

Reference value – where the sample is measured using a validated reference method traceable to a high metrological order or by gravimetric measurement.

Method mean – used if no reference target values are available and the number of participants using the method ≥8

Overall mean – used if no reference target values are available and the number of participants using the method <8

Analyser mean – this is provided on the report for information only and is not used to calculate the target value unless the analyser is regarded as sufficiently different to other systems to justify its own method group e.g. Ortho Vitros.

1.1.1 Reference Values

The ***HDL Cholesterol*** target values are assigned using the CDC Abel-Kendall reference method in an approved CDC network laboratory.

For ***HbA1c*** the target values are assigned using the IFCC methods in an approved IFCC (NGSP) reference laboratory.

All other Reference values are assigned by the Weqas Reference Laboratory.

1.1.2 Uncertainty

The combined standard uncertainty of the reference target value is calculated from the *ISO Guide to the Expression of Uncertainty in Measurement.*

Combined Standard Uncertainty = $\sqrt{\{ (Usample)^2 + (Ustd)^2 + (USRM)^2\}}$

Where

Usample = uncertainty associated with sample precision
Ustd = uncertainty associated with standard preparation
USRM = uncertainty associated with the SRM

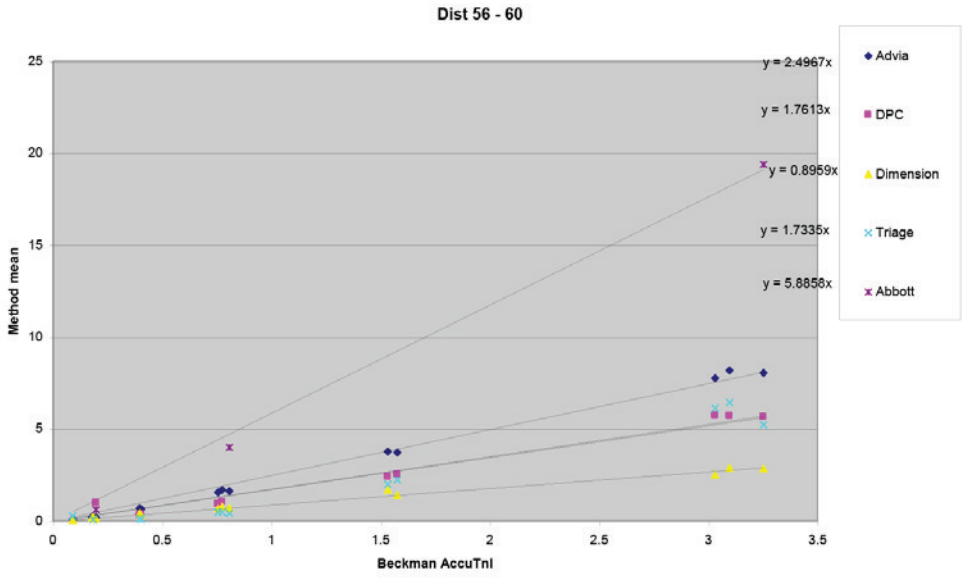
An estimate of the uncertainty of the Robust mean is calculated from:

$$\text{Estimated Uncertainty} = 1.25 \times \frac{SD}{\sqrt{n}}$$

1.2 Comparability Factors

This is used for multimodal data where a wide variation is observed for the overall consensus mean due to the widely different methods used. Typically, this would be used for enzymes, (as activity rather than concentration is measured), Ammonia (wet and dry chemistry systems) and Troponin I (no standardisation). A method specific comparability factor (CF) is calculated for each method by analysing the method data using linear regression analysis against a peer reference method (i.e. IFCC for enzymes, GLDH method for Ammonia and Beckman AccuTnI for Troponin I.). An example for Troponin is given in Figure 1. The results for each laboratory are then adjusted using the CF. Each laboratory's results can therefore be compared with their own method group, the peer reference method and directly compared with the overall mean of all groups. The CF's for each scheme are available on request. Where applicable, the recommended IFCC methods have also been set up in the Weqas Reference Laboratory to give definitive values.

Figure 1 - Relationship between Troponin I methods and the calculation of method specific CF



1.3 Scoring System

For each analyte at each sample point the standard deviation index (SDI) is calculated. This is calculated as: (laboratory result – target value) / Weqas SD. In some EQA Programmes this is known as the Z score. The target value is described in section 1.6.

For each analyte the average SDI is calculated to give an **analyte SDI**. This is calculated as the sum of the absolute numerical values of the individual SDI scores divided by the number of scores. The positive and negative signs are not included in the calculation as this will mask poor performance. An acceptable average analyte SDI does not guarantee acceptable performance across the analytical range and the individual scores must be looked at.

Table 5 - Interpretation of Scoring System Based on SD Index

less than 1	Good - all points within ± 1 SD	
1 - 2	Acceptable	
greater than 2	Unacceptable - Laboratory needs to evaluate the analyte	

The SDI is an index of Total error and will include components of both inaccuracy and imprecision.

Running Score of Lab SDI

This gives a general overview of performance over time. The median (50th centile), and worst SDI scores (97.5th centile) for all laboratories are given for comparison.

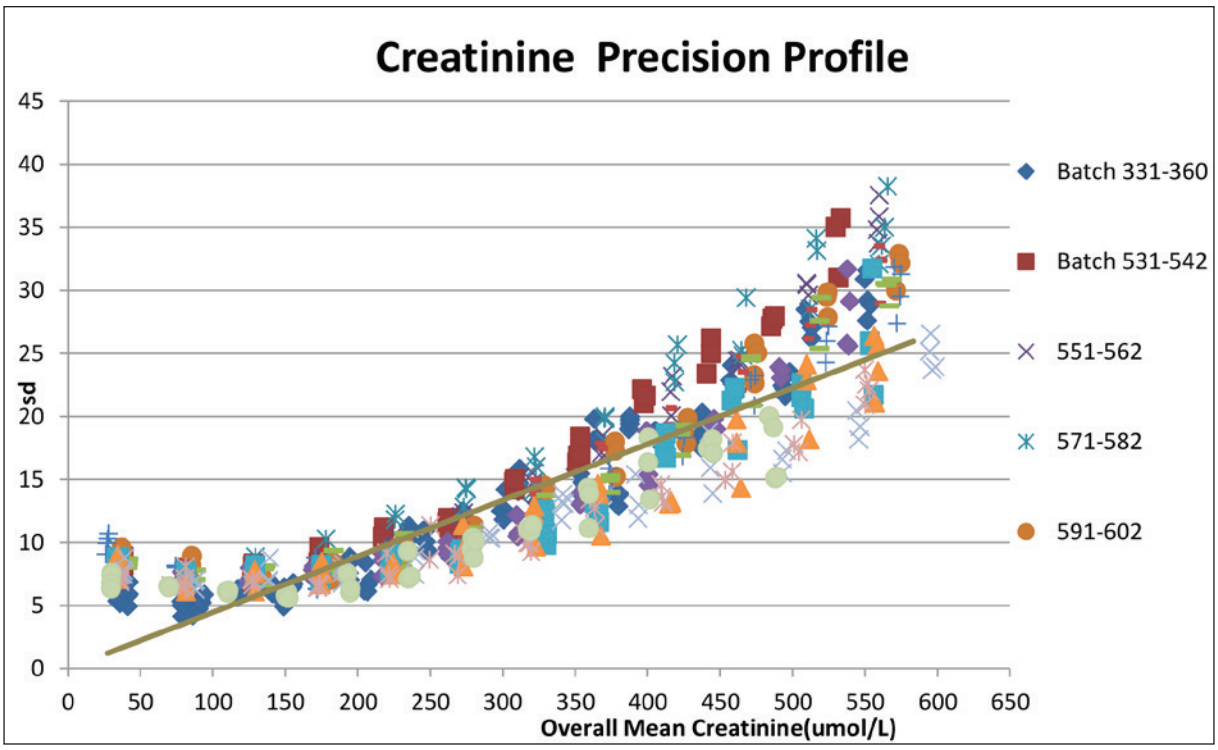
1.4 Performance Criteria

Laboratories must ensure that the analytical quality attained is appropriate for the needs of the clinical service. It is therefore essential that EQA performance criteria should also reflect clinical need. A hierarchical strategy to establish analytical goals was proposed at the European Federation of Laboratory Medicine in Milan in 2014 and is summarized below.

- **Model 1. Based on the effect of analytical performance on clinical outcomes.** This model is the most rationale since it is based on the actual clinical outcome; however, in practice it is applicable only to a few tests since it is difficult to show the direct effect of laboratory tests on medical outcome.
- **Model 2. Based on components of biological variation of the measurand.** This model seeks to minimize the ratio of the analytical noise to the biological signal. Its applicability can however be limited by the validity and robustness of the data on biological variation.
- **Model 3. Based on the state of the art.** This model is the one where data is most easily available. It is linked to the highest level of analytical quality achievable with the currently available techniques.

The models higher in the hierarchy are to be preferred to those at the lower level. Different strategies have been applied to the different analytes in each scheme based on what is achievable. If the biological goals are not achievable, the analytical performance criteria are based on current "state of the art" of the methods. These "state of the art" precision profiles are calculated over several batches over a wide pathological range. The relationship between SD (or CV%) and the analytical concentration is calculated from the line of best fit (often polynomial). Figure 2 shows an example for Serum Creatinine. These analytes are reviewed every 2 years and approved by the Steering Committee.

Figure 2 - Precision profile for Serum Creatinine



1.5 Minimum Analytical Performance Standards (MAPS)

MAPS is a National Quality Assurance Advisory Panel (NQAAP) initiative endorsed by the Professional bodies; the Royal College of Pathologists, ACB, ACP and IBMS. Five analytes have been included in the first pilot: Cholesterol, HDL, Glucose, Creatinine and HbA1c.

MAPS is based on the European Biological Variability Data now hosted by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) at https://biologicalvariation.eu/

For each test the standard has been defined against a critical diagnostic value and reference method at which the MAPS should be assessed, and provide values for Bias, Imprecision (CV) and Total Error (TE).

Table 6 - MAPS Phase 1 Analytes

Analyte	Criteria level	TE %	Bias %	CV %	Sigma	Ref Method
Cholesterol	5 mmol/l	8.5	4	2.7	1.67	CDC
HDL	1 mmol/l	15.9	10	3.6	1.64	CDC
Glucose	7 mmol/l	6.9	2.2	2.9	1.62	ID-GCMS
Glucose	2 mmol/l	10				ID-GCMS
HbA1c	50 mmol/mol	7.7	3.6	2.5	1.64	IFCC
Creatinine	75 umol/l	9.5	5	2.7	1.67	ID-GCMS
For these MAPS, TE = (1.65*imprecision)+inaccuracy						

How does Weqas calculate these parameters and provide a MAPS score?

Weqas has combined the MAPS specifications into a single score called the Sigma Score.

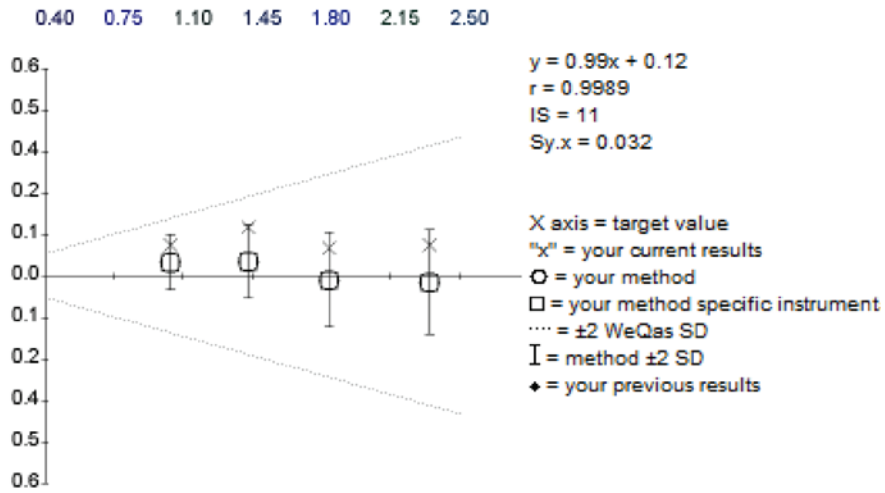
$$\text{Sigma} = [(TE_{maps} - bias_{obs})/s_{obs}]$$

Where TE_{map} is the Total allowable error as defined by MAPS

$Bias_{obs}$ is the laboratory Bias at the critical level and is calculated from the linear regression analysis, y = mx + c (uses 4 results, can be from previous dist). This can only be calculated if the true bias to reference method is known.

S_{obs} is the within run CV(%) and is calculated from the Sy.x. (see section 1.6.1)

Figure 3 - Example of Sigma Score Calculation - Distribution L299 HDL Cholesterol



From the above example for HDL,

Bias

The bias is calculated from the linear regression analysis of the laboratory results against the CDC Reference Laboratory's target values.

From the linear regression analysis equation, y = mx + c, the bias is calculated at the critical level (x), which for HDL is 1 mmol/L.
When x=1 then y=0.99(*1)+0.119 = 1.109, (intercept rounded up on report to 0.12).
Therefore, bias = (y-x)/x*100 = (1.109-1)/1*100 = 10.9%
Interpretation - This is higher than the MAPS allowable bias of 10% and needs action.

Imprecision

Laboratory within run Imprecision, S_{yx} = 0.032 mmol/L
CV = (S_{yx}/ x)*100 = 0.032/1*100 = 3.2%
Interpretation – This is within the MAPS allowable CV of 3.6% and is therefore acceptable.

Sigma Score

Sigma = [(TE_{maps}- $bias_{obs}$)/s_{obs}]
For HDL TE_{maps} = 15.9%
Therefore Sigma = (15.9 – 10.9) / 3.2 = 1.56

The MAPS allowable Sigma is calculated from:

$Sigma_{min}$ = (TE_{maps} – $Bias_{maps}$) / S_{maps}
$Sigma_{min}$ = (15.9-10)/3.6 = 1.64

During the pilot, the only additional information displayed on your report will be the Sigma score.
Laboratory performance that does not meet the MAPS criteria will be highlighted in red.

How does MAPS Score affect poor performance surveillance?

During the pilot, the SDI score will remain as the index for poor performance surveillance and the existing analytical specifications for the SDI calculation will remain unchanged. The Sigma score will however be used to identify methods that do not comply with MAPS and the manufacturers contacted.

1.6 The Weqas Standard Report - An annotated version is provided in Figure 6a and 6b.

The Report outlines the Laboratory Code, Section Code, Distribution Code and sample numbers. The current method code is printed against each analyte. The following table outlines the parameters covered in the Weqas report.

Reported Results	Results as submitted on the "Result Entry form"
Method corrected results	Results adjusted if a method CF is used. Lab result / method CF
Method mean	Estimation of the method mean using a robust algorithm
Method SD	Estimation of the Method SD using a robust algorithm
Analyser mean	Estimation of your analyser group mean using a robust algorithm
Analyser SD	Estimation of your analyser group SD using a robust algorithm
Number of results	Number of results in your method group
Overall mean	Estimation of the overall mean using a robust algorithm
Weqas SD	SD used to calculate SDI and given in graphical representation - fixed for a given level of analyte. Performance criteria = target value ± 2*Weqas SD
Overall number	Number of reported results
SDI	(Laboratory result – target value)/ Weqas SD
Reference values	Target values using validated reference methods
Uncertainty of target value	The standard uncertainty of the target value is calculated from the *ISO Guide to the Expression of Uncertainty in Measurement.*
Non scoring reference value	For information only, used when the reference method procedure gives very different results to routine methods.
Sigma score	Your score based on MAPS criteria.
Analyte SDI	Your Average SDI for the analyte
Overall Section SDI / Lab SDI	Overall SDI for your section or Lab.
Previous SDI	Accumulator of previous SDI scores for your lab
Median All Laboratory SDI	Median (50th centile) SDI for all laboratories for this distribution. SDI< Median indicates good score (top 50% of labs).
97.5th Centile	SDI poor performer indicator. SDI > than this value indicates poor lab score (worst 2.5% of labs).
Correlation coefficient	This is used as an index of within run imprecision, the wider the deviation from 1.000, the wider the scatter of results about the line of best fit.
Standard deviation of the residuals	This is used as an index of within run imprecision, and is provided in the units of the analyte. It gives an indication of standard deviation across the range of samples.
Imprecision score	This is derived from the correlation coefficient.
Linear regression equation	This is used as an index of inaccuracy. The slope should be as close to 1.0 and the intercept should be as close to 0. It provides a measurement of agreement between your results and the target value over a range of samples.

1.6.1 Measurements of Imprecision

The Coefficient of Linear Correlation and the Standard Deviation of the Residuals gives a measure of the dispersion of the points about the best fit line and is therefore an index of precision. The Imprecision Score is derived from the correlation coefficient.

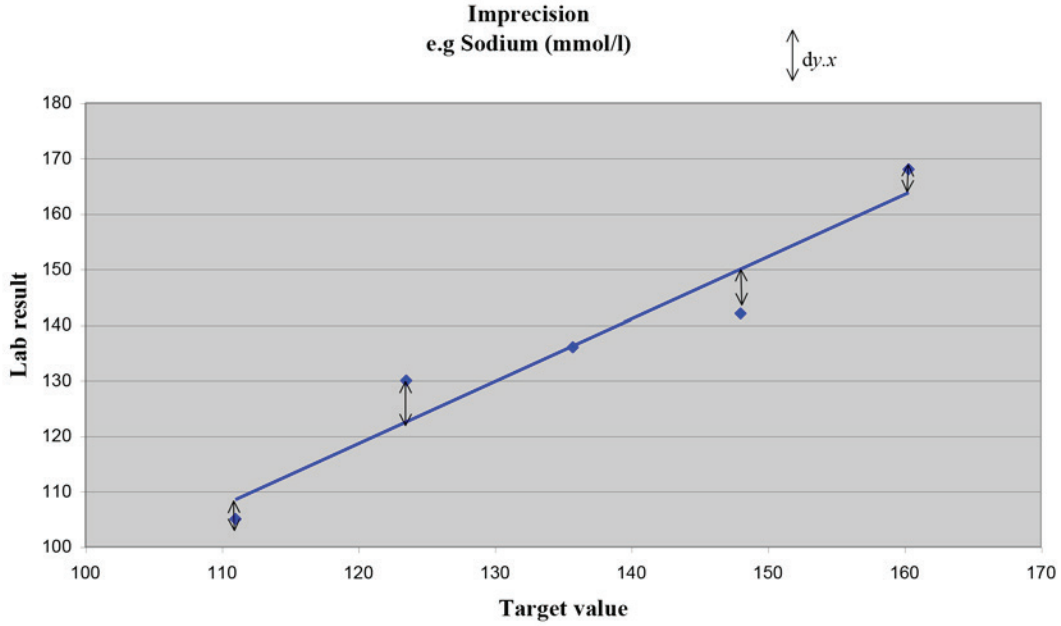
- **Standard Deviation of the Residuals (Sy.x)**

The equation for the Sy.x is:

$$\frac{\sqrt{\Sigma dy.x^2}}{d.f}$$

where y = observed value, d.f = degrees of freedom and ỹ is the value on the line of best fit

Figure 4 - Example of Calculation of the Sy.x



Target	Lab result	Line of fit	Deviation	Dev^2
x	y	$\tilde{y}$	$dy.x = y-\tilde{y}$	$dy.x^2$
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*	$\Sigma dy.x$	$\Sigma dy.x^2$
	int	*-9.17*	0.0	67.36
	r	*0.9812*		
	IS	*187.7*		
	$S_{y.x}$	*4.74*		

The Coefficient of Linear Correlation (r):

The equation for the correlation coefficient is:

$$Correl(X,Y) = \frac{\Sigma(x-\bar{x})(y-\bar{y})}{\sqrt{\Sigma(x-\bar{x})^2\Sigma(y-\bar{y})^2}}$$

- Imprecision score (IS)

The equation for the IS:

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

Table 7 - Interpretation of "r" value and imprecision score

'r' value	Imprecision score	Interpretation
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)

1.6.2 Measurements of Inaccuracy

The Linear Regression Analysis of the laboratory results *(y)* against the target value *(x)* is used as an index of inaccuracy. **Linear regression** produces the slope of a line that best fits a single set of data. The equation $y = mx + c$ algebraically describes a straight line for a set of data with one independent variable where x is the independent variable, y is the dependent variable, m represents the slope of the line, and c represents the y-intercept.

- The accuracy of the line calculated depends on the degree of scatter in your data. The more linear the data, the more accurate the model. Weqas uses the method of least squares for determining the best fit for the data. The calculations for m and c are based on the following formulas:

$$m = \frac{\Sigma(x-\bar{x})(y-\bar{y})}{\Sigma(x-\bar{x})^2} \qquad c = \bar{y} - m\bar{x}$$

A deviation from a slope (m) of 1.00 indicates possible systematic proportional error.

The intercept (c) gives an indication of the systematic absolute (blank) error.

$y = mx + c$ is not calculated where the 'r' value is below 0.9.

1.6.3 Bias Plots

The bias plot gives a graphical representation of each laboratory's values compared with the "target" values. The *"x"* axis line represents the "target" values. The *"y"* axis has a scale that spans ± 3 SD from this line, and the 2 SD limits are marked on the graph (…) Standard deviation limits used in the report are calculated from the analyte performance criteria.

Left hand graph

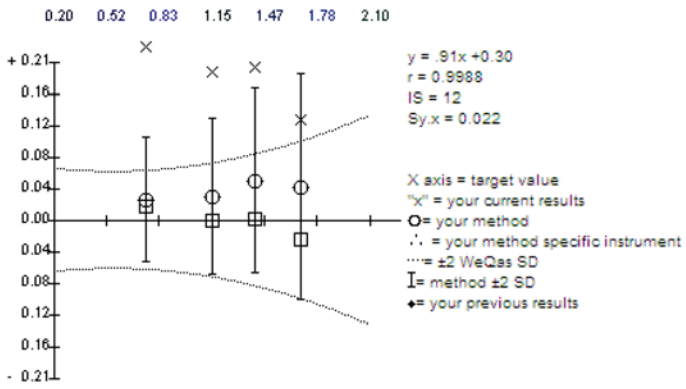
This represents the current distribution. *"x"* indicates the laboratory bias at each level of analyte; "o" indicates the method mean bias and "□" the instrument mean bias. The bar lines relate to the ± 2 SD limits around the method mean. At the right hand side of each graph the relationship between the laboratory's results and the target value is expressed as a straight line equation, 'y = mx + c'. The Coefficient of Linear Correlation, (*r*) the Standard Deviation of the Residuals (Sy.x), and the Imprecision Score (IS), are also given.

Right hand graph

This provides a cumulative bias plot of the data over 6 distributions and shows a graphical display of the between batch imprecision.

Figures 5a and 5b - Bias Plots

This Distribution *NF*



Previous Distributions

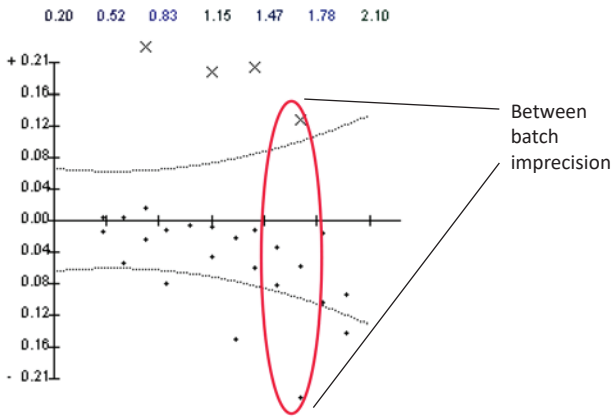


Figure 6a

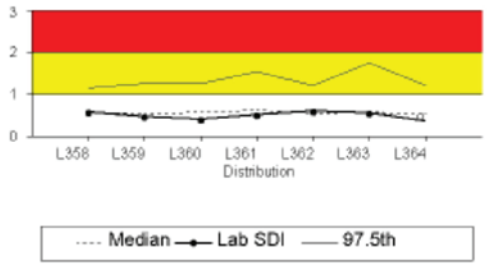
Standard Report Format - Easy to read **cumulative reports**

Weqas

QA Officer
Biochemistry
St Elsewhere
Inacity
Someshire
KK1 4ZX

Manager's performance summary sheet.
Total Error - measured as ***Standard Deviation Index.*** -includes components of inaccuracy and imprecision.

This Distribution	
Overall Lab SDI:	0.36
Median All Laboratory:	0.52
97.5th centile:	1.21



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

Section SDI scores for this distribution

Section	Harris (700)	Tweed (800)
Overall	**0.41**	**0.31**
Cholesterol	0.46	0.30
Triglyceride	0.42	0.35
HDL Cholesterol	0.22	0.20
LDL Cholesterol	0.55	0.39

For each sample for each analyte:
SDI = (Lab result – *Target value) / Weqas SD*CF

Running Score of Lab SDI - gives a general overview of performance over time. The best and worst SDI scores for all laboratories are given for comparison.

Analytical goals (***Weqas SD)*** are based on either:
•Precision profiles - reflecting the "state of the art".
•Clinical decision goals -e.g. cholesterol
•Biological variation- e.g. HbA1c

Analyte SDI for each Section at a glance.
Colour coded for performance.

SDI Code	Meaning
N/A	Not enrolled for this analyte
?	Analyte enrolled but no results returned
N/S	This analyte not scored
**	SDI score greater than 2

Hierarchy of target values
1 Reference method (if available for all samples)
2 Method mean (if n > 8)
3 Overall mean

Comments:
Information relating to this distribution can be displayed in this text box

Figure 6b

Analyte Specific data sheet - detailed assessment of performance for each analyte

Reference values. If Reference values are available they are used to calculate the SDI and replace the overall mean as the target value on the bias plot.

Scheme: Lipid. Distribution Code: L364.
Distribution Date: 26/03/18. Final. Report Issued: 20/04/18

Cholesterol (mmol/l)		1	2	3	4	Analyte SDI
Reported Result		6.80	2.50	4.60	4.80	
Method Corrected Result		6.800	2.500	4.600	4.800	
Cholesterol oxidase	Mean	7.092	2.617	4.876	4.963	
	SD	0.225	0.093	0.183	0.169	
	Number	174	174	174	174	
	Uncert.	0.0214	0.0088	0.0174	0.0161	
Cobas C Module	Mean	7.006	2.587	4.811	4.901	
	SD	0.123	0.075	0.112	0.106	
	Number	98	98	98	98	
	Uncert.	0.0155	0.0094	0.0142	0.0134	
Overall	Mean	7.081	2.615	4.868	4.953	
	SD	0.233	0.090	0.189	0.174	
	Number	179	181	179	181	
	Uncert.	0.0218	0.0084	0.0176	0.0161	
Reference Values CDC		7.038	2.606	4.867	4.963	
Ref. Value Uncertainty		0.0140	0.0000	0.0000	0.0000	
Non-scoring Reference Values ID-GCMS		7.110	2.590	4.850	4.970	
WeQas SD		0.301	0.111	0.207	0.210	
SDI		-0.79	-0.95	-1.29	-0.77	0.95

Sigma Metrics

Critical Level 1: 5.0 mmol/l

Minimum Acceptable score	1.67	Critical Level 1 Sigma score	3.8
MAPS Allowable TE	8.5%		
MAPS Allowable bias %	4.0%	Lab |bias| %	3.9%
MAPS Allowable CV %	2.7%	Lab CV %	1.2%

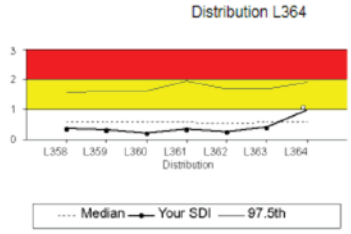
Please note: Linear regression uses CF corrected data.

Total Error

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

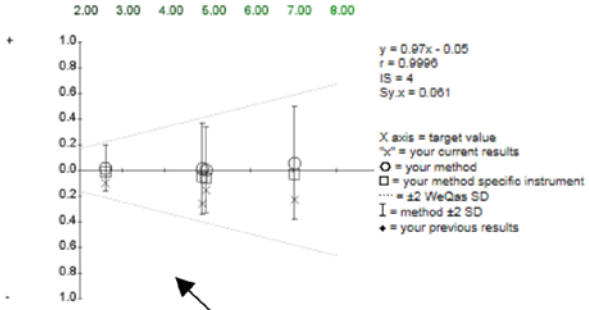
This Distribution L364
Your average analyte SDI for the 4 samples is 0.95

Previous SDI

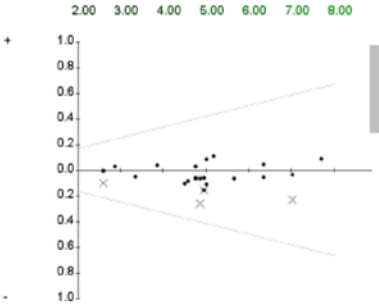


Sigma Score using MAPS criteria.

This Distribution *L364*



Previous Distributions



Analytical goals
2 x Weqas SD

Bias Plot (Bland-Altman)
Current distribution (from data in table) including lab, method and instrument performance.

Right hand plot shows **Previous distribution** results, including current distribution

Precision and accuracy indicators

Precision

This Distribution L364	Previous Distributions	L363	L362	L361	L360	L359	L358
Sy.x = 0.061 mmol/l	**Sy.x**	0.046	0.092	0.098	0.058	0.074	0.034
IS = 4	**IS**	6	9	11	6	11	3

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 L364	Previous Distributions	L363	L362	L361	L360	L359	L358
Systematic proportional error (calibration) -2.96%	**Proportional (%)**	-4.76	-0.40	2.58	0.31	3.60	-0.28
Systematic constant error (blank) - 0.049 mmol/l	**Constant (mmol/l)**	0.121	0.020	- 0.153	- 0.005	- 0.175	- 0.061

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.

1.7 Problem Solving

The following pages include a rule based problem solving guide. The power of prediction identifies the cause of the problem often before the analysis is out of control, i.e. outside ± 2 SD. The sensitivity of statistical parameters to different types of error is explained. The types of errors are shown graphically in Figure 7. Problem solving flow charts (Figures 8a and 8b) also allow for a simplified procedure for identifying problems and verifying corrective action.

Table 8 - Sensitivity of Statistical Parameters to Different Types of Errors

	Type of Error				
	Imprecision	Inaccuracy (Systematic)			
	Random	*Curvilinear*	*Proportional*	*Mixed*	*Constant*
Slope, m	No	Yes	Yes	Yes	No
y intercept, c	No	Yes / No	No	Yes	Yes
Standard error, Sy.x	Yes	Yes	No	No	No
Corr. coefficient, r	Yes	Yes	No	No	No

Imprecision: Errors of imprecision should be corrected first. A small random error is acceptable.

Inaccuracy: Systematic errors can be eliminated by appropriate improvement in methodology.
A small systematic error is tolerable. This depends on the clinical usefulness of the method.

If your results show an error: look at the Problem Solving Guide flow diagram and identify the error.

On the Bias Plot the y = mx + c assumes a linear relationship between the laboratory results and the Ideal Line. For this reason large random errors, identified as an IS > 150 or a wide Sy.x will invalidate this equation. **A line drawn through the points will aid in identifying the type of error.**

Start by asking the question - Is it Imprecision?

Check for causes of imprecision in the following order:

- Exclude apparent imprecision due to curvilinear data.

- Exclude clerical errors (blunder error).

- Check for causes of imprecision, e.g. inexperienced operators (analysts), faulty equipment, inappropriate methods.

Once you are happy with your analytical precision you can then look for causes of inaccuracy.

Is it Inaccuracy?

Inaccuracy can be due to:

- *Curvilinear data:*	Reagent or standard deterioration.
- *Systematic constant:*	Usually blank due to reagent, serum or instrument zero.
- *Systematic proportional:*	Usually due to calibration, standards.
- *Mixed systematic:*	On one point calibration with a cross-over at or near a calibration point (pivoting about calibration point), check zero calibration point, i.e. reagent blank, serum blank, instrument zero and then follow guide as for proportional systematic error. For a two point multi calibration with cross-over at or near one point, check other calibrators and/or zero point.

Figure 7 - Errors in Accuracy

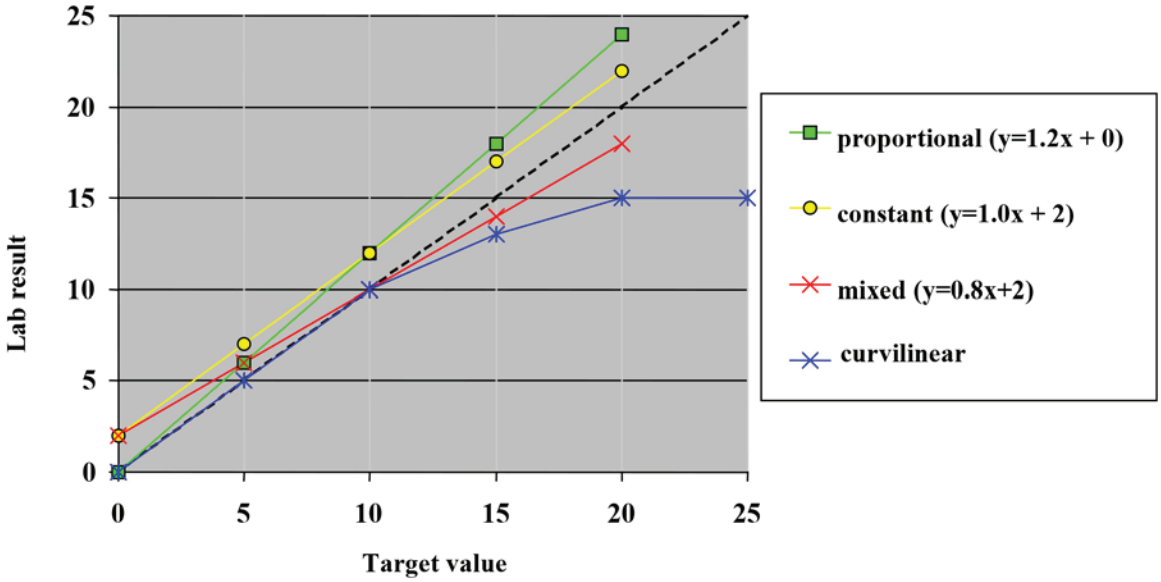


Figure 8a - Problem Solving Flow Chart

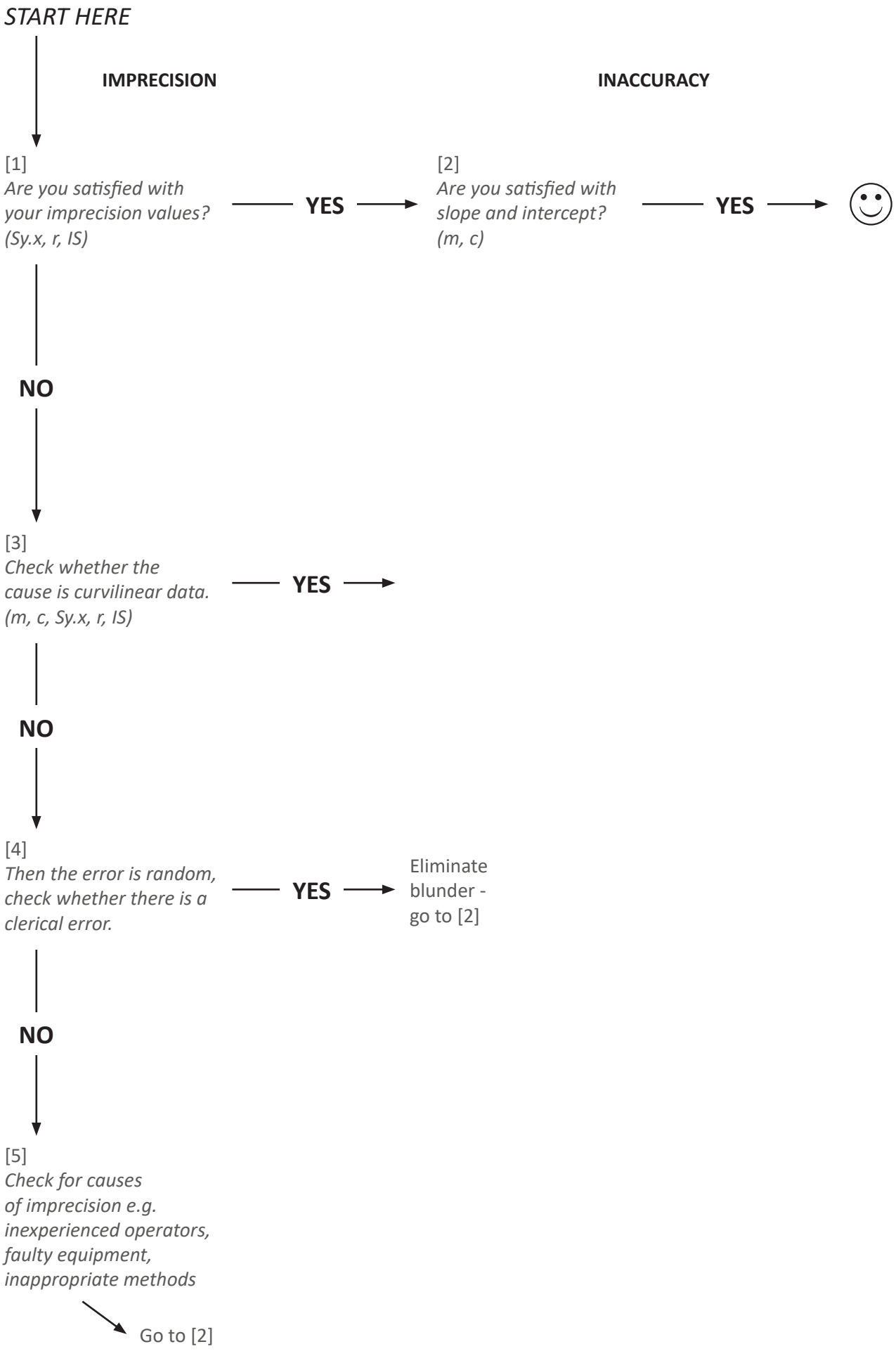


Figure 8b - Problem Solving Flow Chart

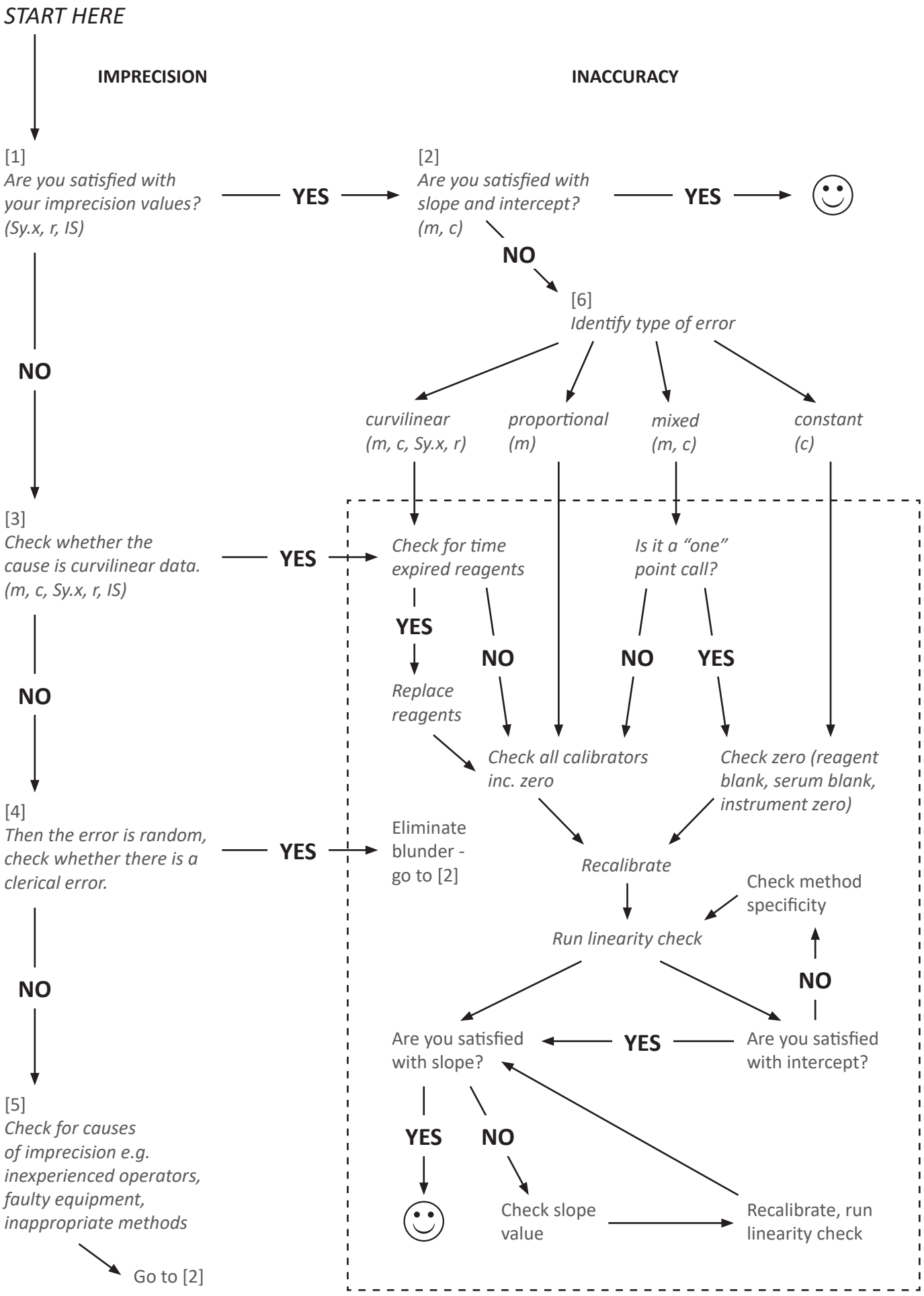


Figure 9a - Bias Plot - With Explanation

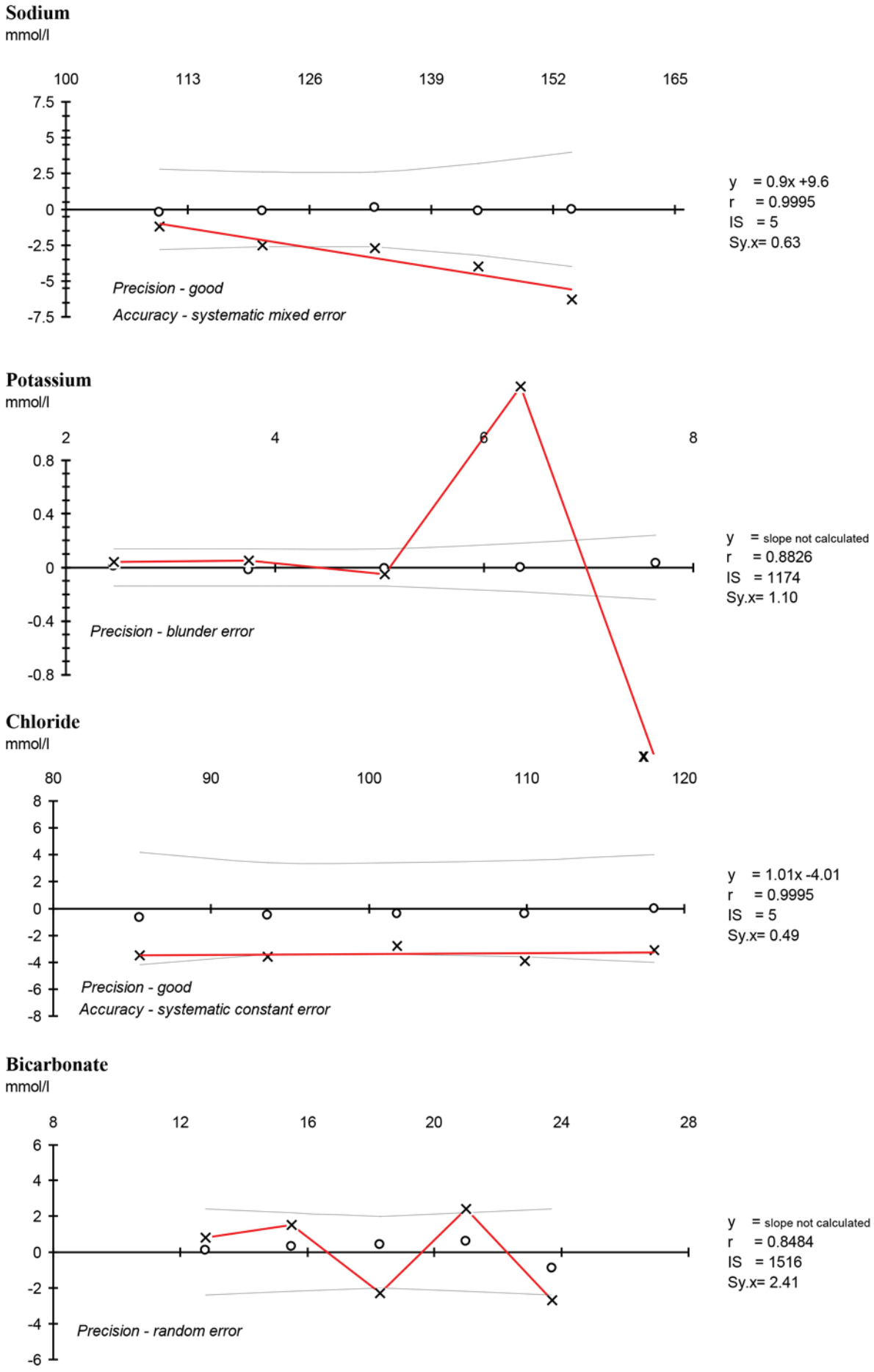
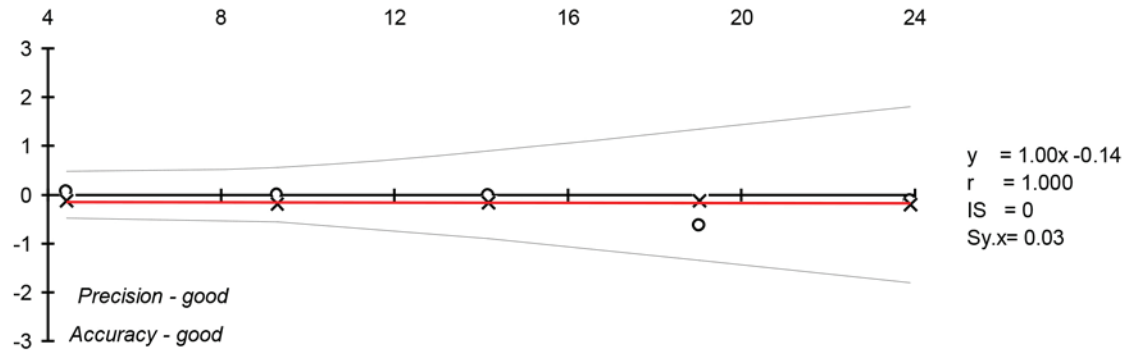
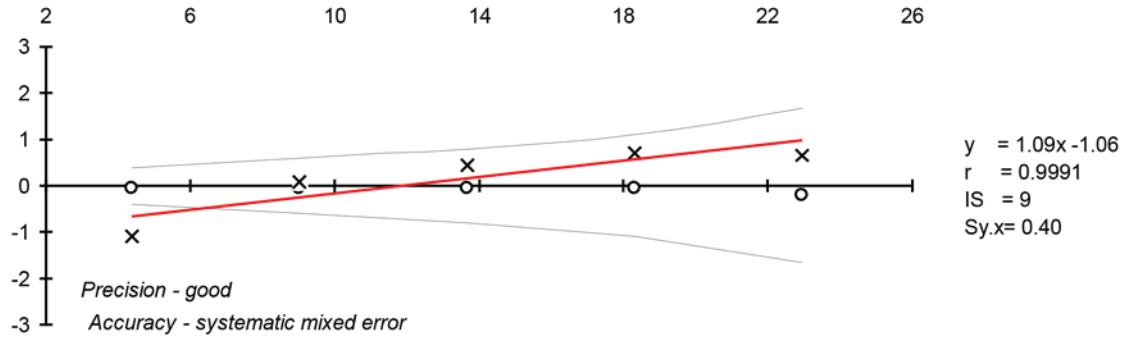


Figure 9b - Bias Plot - With Explanation

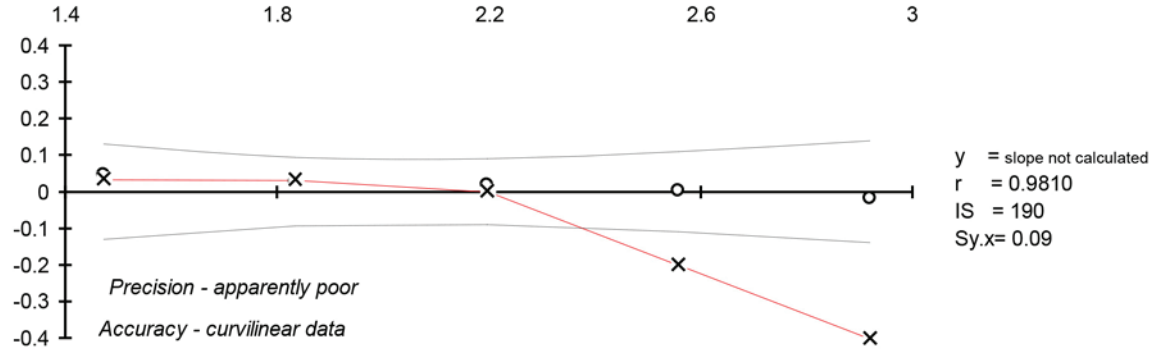
Urea
mmol/l



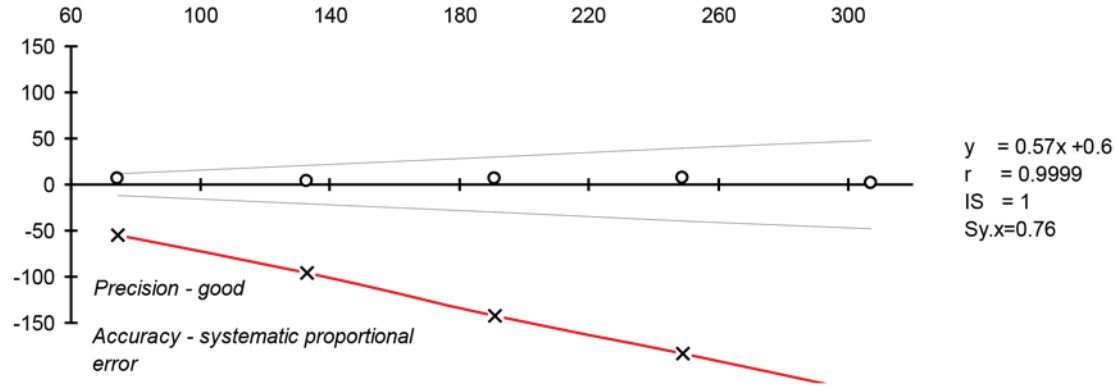
Glucose
mmol/l



Calcium
mmol/l



ALP
IU/L



Use of the Problem Solving Guide for Identifying Errors in Lab Report

Sodium (Figure 9a)

[1] Imprecision - satisfactory [5] Inaccuracy - identify error
[6] 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

Potassium (Figure 9a)

[1] Imprecision - unsatisfactory, r = 0.8826, Sy.x = 1.1 mmol/L
[2] Not curvilinear
Error - blunder
Cause - clerical error, samples 4 and 5 were transposed

Chloride (Figure 9a)

[1] Imprecision - satisfactory [5] Inaccuracy - identify error
[6] c = -4.0 mmol/L
Error - systematic absolute. Results low by 4.0 mmol/L over the whole range
Cause - incorrect serum blank compensation

Bicarbonate (Figure 9a)

[1] Imprecision - unsatisfactory, r = 0.8484, Sy.x = 2.4 mmol/L
[2] Not curvilinear
Error - random
Cause - faulty syringe on instrument

Urea (Figure 9b)

[1] Imprecision – satisfactory [5] Inaccuracy - satisfactory

Glucose (Figure 9b)

[1 Imprecision - satisfactory [5] Inaccuracy - identify error
[6] m = 1.09, c = -1.06 mmol/L
Error - mixed. One point calibration at 9 mmol/L
Cause - incorrect instrument zero

Calcium (Figure 9b)

[1] Imprecision - unsatisfactory, r = 0.9810, Sy.x = 0.09 mmol/L
[2] Error - curvilinear data
Cause - time expired reagents

ALP (Figure 9b)

[1] Imprecision - satisfactory [5] Inaccuracy - identify error
[6] 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.

Case studies of EQA reports including interpretive comments are available to download from our website. Please use the following link and search for 'Case Studies'.
http://www.weqas.com/resourcelibrary/

1.8 Other Reports

A number of additional reports are provided which can be accessed online.

Figure 10 - Analyser reports

Detailed performance reports allowing comparison with all other returns in your own method and instrument group can be accessed via links in the individual analyte report pages.

Reported Results for all sections with Instrument Means and SDs

Distribution: **OI**
Distribution Date: **1 Aug, 2011**
Analyte: **Magnesium**
Method: **Magon / Xylidyl blue**
Instrument: **Advia 1200/1650/1800/2400**

		Distribution Code : OI	Sent on: 1/08/11		
Magnesium (mmol/l)		**1**	**2**	**3**	**4**
AAE		1.58 *	1.56	0.55	1.13
BY		1.71	1.57	0.55	1.21
BY		1.67	1.56	0.50	1.15
CH		1.79	1.63	0.46	1.18
CH		1.79	1.64	0.50	1.20
CH		1.75	1.62	0.52	1.19
DB		1.72	1.60	0.40	1.14
DB		1.62	1.52	0.47	1.13
DS		1.69	1.55	0.50	1.16
DS		1.68	1.55	0.48	1.14
EB		1.58 *	1.50 *	0.46	1.09
EB		1.74	1.62	0.52	1.19
EC		1.77	1.63	0.51	1.19
EK		1.77	1.64	0.53	1.21
EK		1.79	1.64	0.51	1.21
EQ		1.74	1.59	0.59	1.26
EQ		1.76	1.60	0.52	1.22
KH		1.81	1.66	0.51	1.21
KH		1.73	1.61	0.50	1.18
KJ		1.72	1.58	0.44	1.18
KJ		1.72	1.59	0.50	1.19
KK		1.80	1.66	1.21 *	0.52 *
KK		1.80	1.64	0.49	1.20
KK		1.83	1.67	0.52	1.23
NW		1.77	1.62	0.52	1.21
NW					
NW		1.78	1.66	0.53	1.20
SS		1.80	1.66	0.52	1.23
Overall	Mean	1.702	1.573	0.502	1.169
	SD	0.063	0.055	0.023	0.041
	CV	3.73	3.53	4.60	3.48
	Number	223.00	222.00	232.00	232.00
	Reference Value FAAS / FAES	1.698	1.572	0.484	1.149
	Reference Value NS				
Instrument Specific Data					
Magon / Xylidyl blue	Mean	1.743	1.609	0.509	1.187
	SD	0.052	0.037	0.036	0.036
	CV	2.96	2.29	7.05	3.05
	Number	36.00	36.00	37.00	37.00
Key: Red - Outside Range. * - Instrument Outlier					

Figure 11 - Method Summary reports

A selection of Method summary reports are e-mailed with your PDF reports and attached to your 'report ready' email notification. Additional summaries for all methods / instruments for all analytes within your Registered Scheme are available to download online.

Mainline Chemistry Summary Sheet Distribution QH

Distribution:	QH	Weqas				
Distribution Date:	02-Nov-15					
Analyte:	**Creatinine (µmol/L)**					
Method	**Instrument**		**1**	**2**	**3**	**4**
		Overall Mean	352.8	350.0	43.3	583.8
		Overall SD	13.7	13.9	5.1	25.6
		Est. Uncertainty of Consensus	0.84	0.85	0.31	1.56
		Overall Number	268	270	275	269
		Reference Value ID-GCMS	351.9		44.3	583.2
Jaffe - IDMS		Method Mean	347.7	345.6	40.9	571.4
		Method SD	13.8	14.0	4.6	24.9
		Est. Uncertainty of Consensus	1.08	1.09	0.36	1.98
		Number	162	163	165	158
	Advia 1200/1650/1800/2400	Instrument Mean	342.4	341.5	37.0	571.8
		Instrument SD	4.7	5.7	3.1	6.5
		Number	16	16	16	15
	AU2700/AU5400/AU5800	Instrument Mean	341.1	338.8	40.8	565.1
		Instrument SD	8.8	8.1	5.1	15.5
		Number	21	20	20	21
	AU400/600/640/680	Instrument Mean	341.9	341.3	38.0	563.5
		Instrument SD	7.1	6.9	1.5	13.6
		Number	16	16	16	16
	Architect	Instrument Mean	367.2	366.2	45.3	617.3
		Instrument SD	5.7	6.5	1.1	8.3
		Number	24	24	24	24
	DX	Instrument Mean	356.3	362.2	37.6	595.8
		Instrument SD	2.4	5.3	1.6	5.2
		Number	6	6	5	6
	Daytona	Instrument Mean	327.3	324.5	39.2	537.0
		Instrument SD	19.3	21.3	7.5	33.7
		Number	13	14	13	14
	Cobas C Module	Instrument Mean	347.6	345.0	41.0	559.8
		Instrument SD	10.1	8.9	2.9	15.3
		Number	59	58	61	57

Figure 12 - “End of Batch” report

Material is prepared in a number of Programmes to cover more than one distribution, e.g. a batch of mainline chemistry samples consists of 8 levels and each level is distributed on 4 or 5 occasions over a 10 month period. This allows calculation of your between batch imprecision.

The report provides the mean, SD and coefficient of variation (CV%) of your results for each level over this time period. Your CV is then compared with the median CV of all methods and the median CV of your method.

Lab Code: **AE** . Section Name: **Aeroset 1**. Scheme: **Mainline Chemistry**. Distribution Range: **KR - LA**

Analyte: Potassium

Method: **Indirect ISE**	M591	M592	M593	M594	M595	M596	M597	M598	M599	M600	M601	M602
Section Stats												
Mean reported results	1.77	2.23	2.63	3.14	3.63	4.07	4.56	5.11	5.56	6.07	6.59	7.03
SD reported results	0.03	0.01	0.05	0.04	0.03	0.07	0.08	0.08	0.04	0.07	0.02	0.10
CV(%) reported results	1.66	0.52	1.95	1.36	0.69	1.74	1.86	1.48	0.73	1.07	0.23	1.44
Number of results	4	3	3	4	3	2	4	3	3	4	3	3
Method Result Stats												
Mean method mean	1.83	2.30	2.76	3.23	3.71	4.19	4.68	5.16	5.66	6.14	6.63	7.14
Median CV	2.67	2.44	2.01	1.55	1.53	1.35	1.09	1.12	1.02	0.94	0.88	0.83
Overall Result Stats												
Median CV	2.67	2.44	2.00	1.55	1.53	1.36	1.10	1.12	1.02	0.94	0.88	0.84

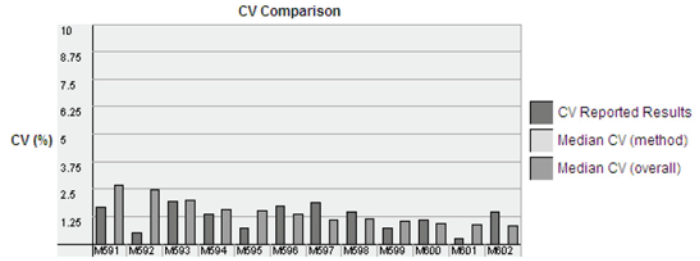


Figure 13 - Regional / Network reports

Using the “end of batch” data, reports can also be generated to compare your performance within your region or network. The report provides a tabular and graphical representation of the deviation (absolute or %) from the group mean for each laboratory for each analyte.

The Weqas performance criteria is also provided on the graph for information. These reports are available to print from your browser, or e-mailed in PDF format to your e-mail address.

Absolute Deviation from Regional Means

		B291	B297	B300	B296	B301	B292	B293	B294	B295	B298	B299	B302
FH	Advia 2400 1	-0.59	-9.31	-10.89	-5.39	-14.48	-2.56	-3.67	-5.22	-7.38	-6.15	-10.04	-11.82
FH	Advia 2400 2	-1.92	-11.48	-18.52	-9.36	-13.35	-2.92	-4.20	-5.86	-7.84	-5.65	-14.51	-14.05
GF	Beta	1.21	5.82	9.58	9.14	8.08	2.24	1.13	4.21	0.06	8.95	0.72	6.72
GF	Alpha (4)	1.21	3.49	11.58	7.81	16.42	3.24	2.47	6.88	3.72	11.62	11.72	10.72
KJ	ARCHITECT 2	0.88	11.49	8.25	3.48	2.42	1.91 *	1.13	4.21 *	3.39	-3.88	2.06	-0.62
KJ	ARCHITECT 1	-0.79	6.49 *	1.25 *	-5.69	0.92	0.91 *	3.13	1.21 *	8.06	-4.88	10.06	9.05
KJ	ARCHITECT 1	3.21 *	16.49 *	9.25 *	16.81 *	-	-	-	-	-	-	-	-
	Weqas SD	2.31	8.61	12.09	7.39	12.90	3.24	4.27	5.34	6.41	9.47	10.93	14.24

* - not included in group mean

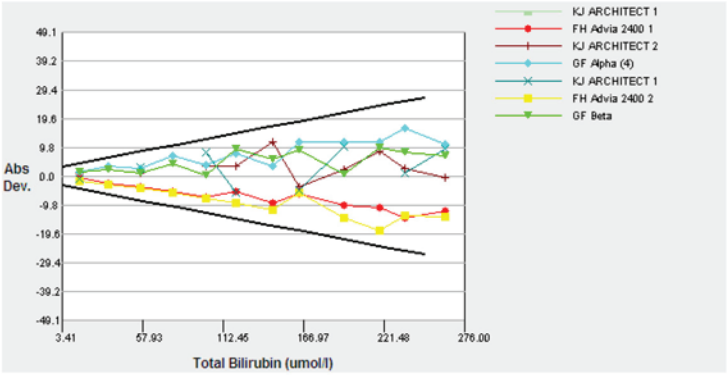
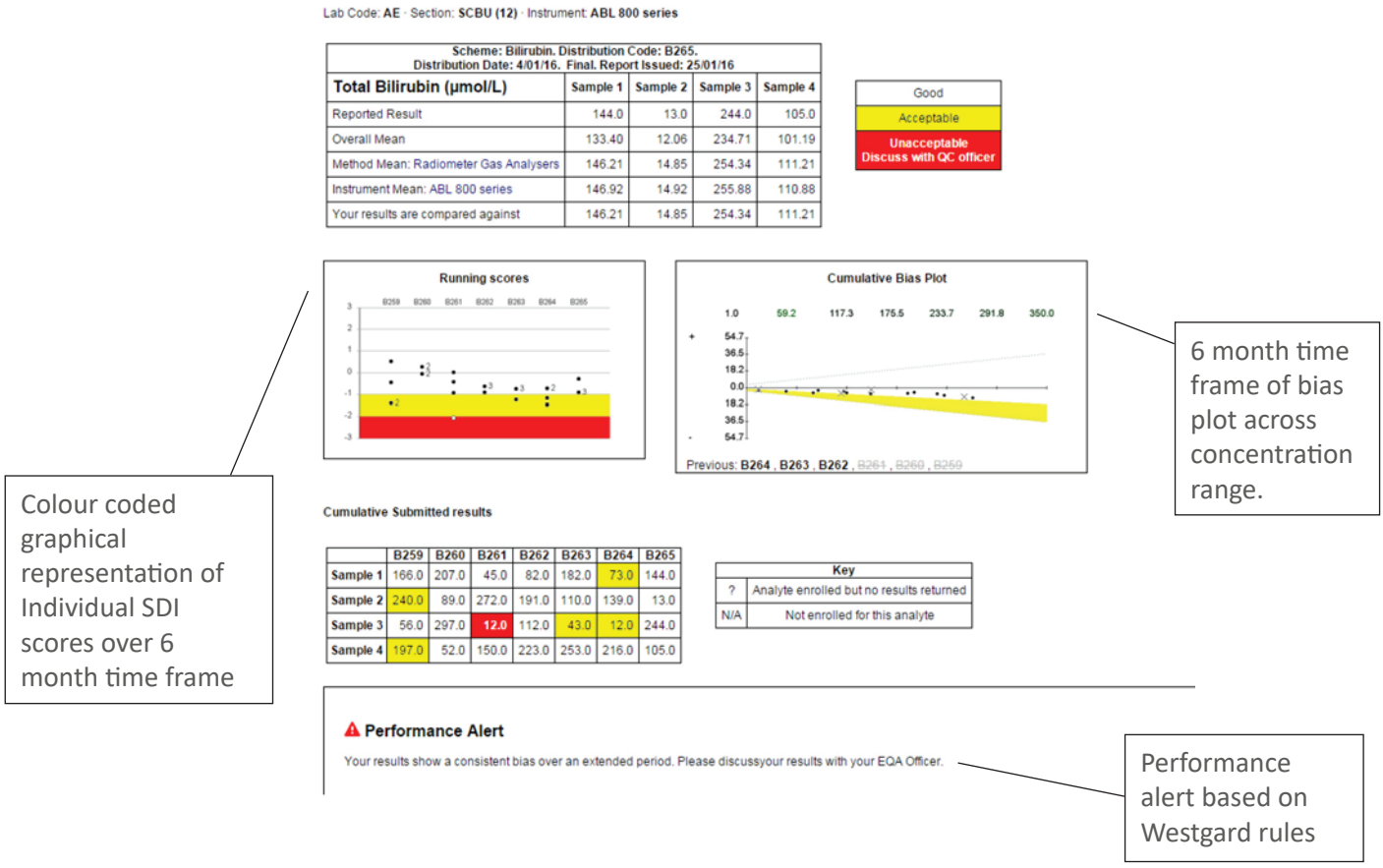


Figure 14 - Simplified Reports

An alternative simplified report is available as an alternative to the Standard report. Identical statistical analysis and data evaluation is undertaken, however the report is simplified to colour blocks and a performance alert for non laboratory personnel.

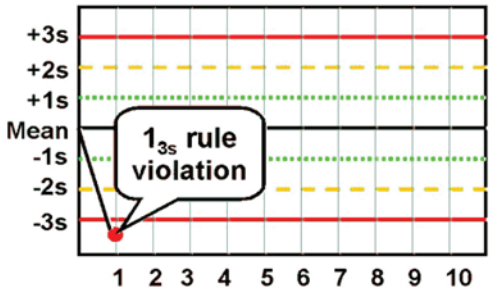


Colour coded graphical representation of Individual SDI scores over 6 month time frame

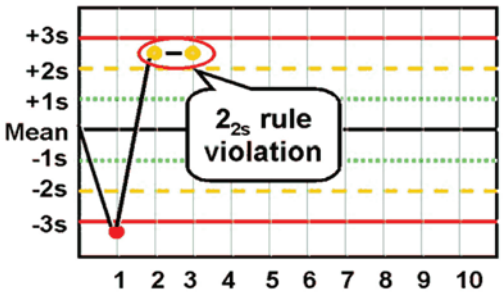
6 month time frame of bias plot across concentration range.

Performance alert based on Westgard rules

The following rules are used for the Performance alert.



At least 1 result with SDI > 3



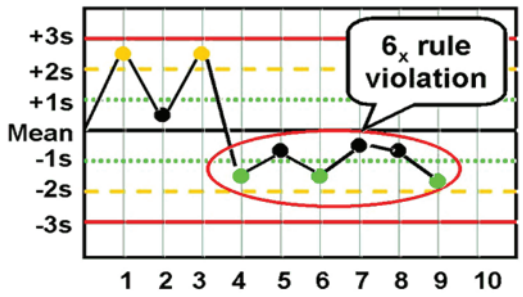
At least 2 results with SDI > 2

If number of samples in current distribution ≥ 2 then applies to this dist only.

If number of samples in current = 1 then applies to this and at least one in previous distribution.

Consistent Bias in one direction.

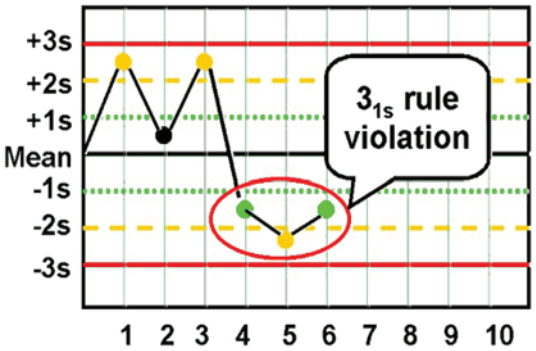
This is calculated over several distributions and will depend on the number of samples distributed per round e.g. if 3 samples are distributed per round, then the rule will be calculated over 2 distributions.



# samples in current with analyte	Number of samples overall to consider	trigger
1	6 samples 6 distributions	6_X: 6 samples with SDI > 0.2 ***or*** 6 samples with SDI < -0.2
2	6 samples 3 distributions	6_X: 6 samples with SDI > 0.2 ***or*** 6 samples with SDI < -0.2
3	6 samples 2 distributions	6_X: 6 samples with SDI > 0.2 ***or*** 6 samples with SDI < -0.2
4	8 samples 2 distributions	8_X: 8 samples with SDI > 0.2 ***or*** 8 samples with SDI < -0.2
5	10 samples 2 distributions	10_X: 10 samples with SDI > 0.2 ***or*** 10 samples with SDI < -0.2
6	6 samples 1 distribution	6_X: 6 samples with SDI > 0.2 ***or*** 6 samples with SDI < -0.2

At least 3 results > 1 SDI.

This is calculated over several distributions and will depend on the number of samples distributed per round e.g. if only 1 sample is distributed per round, then the rule will be calculated over 3 distributions.



# samples in current with analyte	Number of samples overall to consider	trigger
1	3 samples 3 distributions	3_{1s}: 3 samples with SDI > 1 ***or*** 3 samples with SDI < -1
2	4 samples 2 distributions	4_{1s}: 4 samples with SDI > 1 ***or*** 4 samples with SDI < -1
3	3 samples 1 distributions	3_{1s}: 3 samples with SDI > 1 ***or*** 3 samples with SDI < -1
4	4 samples 1 distributions	4_{1s}: 4 samples with SDI > 1 ***or*** 4 samples with SDI < -1
5 or more	All in current 1 distribution	4_{1s}: 4 samples with SDI > 1 ***or*** 4 samples with SDI < -1

2. Statistical Analysis - Qualitative Programmes

2.1 Target Value Assignment

The spiked values are used to determine the target value, verified whenever possible by quantitative analysis. For endogenous samples the result from quantitative analysis is used. When quantitative data is not available, interpretation is based on the majority percentage of responses from participants.

2.2 Scoring System

The scores broadly reflect clinical importance. A correct result (in agreement with interpretive comment) is given a score of 0.

A sliding scale score of between 1 and 5 is assigned for incorrectly identified results, where 5 represented a gross misclassification of the result.

A negative result for a positive sample is given a score of 3 to 5 depending on the concentration of the positive sample.

A positive result for a negative sample is given a score of 2 or 3.

Equivocal comments (for further investigation) for a positive sample are given a score of 1 to 3 depending on the concentration of the positive sample.

An equivocal comment (for further investigation) for a negative sample is given a score of 1.

The sensitivities of the methods, the intended purpose of the kits, whether “rule in” or “rule out” are also taken into account in the scoring. In general, a missed positive sample is given a larger penalty than a misclassified negative as this could lead to missed diagnosis or inappropriate treatment whilst an incorrect negative tends to lead to less severe clinical consequences such as inappropriate further investigation.

Table 9 - Qualitative Scores

Lab Result	Target Value	Score
+ve	+ve	0
equivocal	+ve	1, 2 or 3
-ve	+ve	3, 4 or 5
-ve	-ve	0
equivocal	-ve	1
+ve	-ve	2 or 3

Individual sample scores are added together and averaged for the distribution to provide an overall analyte score. However, a negative for a negative result score of 0 is not included in the overall analyte score.

Table 10 - Interpretation of Scoring System

When the individual score is:

Score	Interpretation
0	Good
1	Acceptable
2	Warning
> 2	Unacceptable

These Scores are treated in the same way as SDI scores for Performance surveillance. Please refer to Section 6, Performance Surveillance.

2.3 The Weqas Report

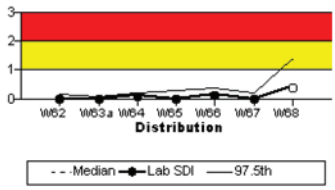
An example of a typical participant's report for the Pregnancy Testing scheme is given below. Each report includes the scoring criteria, a summary of the qualitative results, the broad method used (manufacturer), and method specific performance.

Figure 15 - Manager's Summary Report

office@weqas.com
Scheme Organiser:
Annette Thomas

Lab: AE . Scheme: Urine Pregnancy Testing. Distribution Code: W68.
Final. Report Issued: 5/10/11

This Distribution	
Overall Lab SDI:	0.40
Median All Laboratory:	0.00
97.5th centile:	1.33



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

Section SDI scores for this distribution

Section	2TB2	Clinical Research Facility	Dermatology	EAU - Lisa Waters	EAU - Medical A1 Link	EAU - Surgery	Emergency Gynae	FP Broad Street	FP Butetown
Overall	**1.00**	**0.00**	**0.00**				**0.00**	**0.00**	
Qualitative HCG (High Sensitivity)	1.00 (avg)	0.00 (avg)	0.00 (avg)	?	?	?	0.00 (avg)	0.00 (avg)	?
Section	**FP Cardiff Royal**	**FP Gabalfa**	**FP Grangetown**	**FP Heath, C/O ANC**	**FP Llanrumney**	**FP Llantwit**	**FP Park View**	**FP Penarth**	**FP Roath**
Overall	**0.00**	**1.00**	**0.00**	**0.00**	**0.00**	**0.00**		**0.00**	**0.00**
Qualitative HCG (High Sensitivity)	0.00 (avg)	1.00 (avg)	0.00 (avg)	0.00 (avg)	0.00 (avg)	0.00 (avg)	?	0.00 (avg)	0.00 (avg)

SDI Code	Meaning
N/A	Not enrolled for this analyte
?	Analyte enrolled but no results returned
N/S	This analyte not scored
**	SDI score greater than 2

Please note: Method and Instrument Summary reports are available to download via the 'Lab Stats' or 'Section Stats' menu.

If you don't currently have interactive access , please contact WEQAS for a registration form on 02920 314750.

Comments:

	Sample 1	Sample 2	Sample 3
Urine Source	Urine from non pregnant donor	Urine from pregnant donor diluted to approx 29iu	Urine from pregnant donor diluted to approx 336iu
Interpretation	Negative	Weak Positive	Positive

For interpretation purposes, a sample is regarded negative at a concentration less than 20 IU/L (equivocal results may be produced at a concentration range of 10-20 IU/L and therefore no penalty is given for returning a positive or weak positive result in this equivocal range.) However reporting positive results for a concentration of < 10 IU/L will incur a penalty.

A sample is regarded positive at a concentration >20 IU/L.

Figure 16 - Individual Selection Report

The individual section report includes a graphical representation of the participant's results compared with other participants using the same method (white bar), results for all methods (grey bar) and the correct interpretation based on the quantitative result (green bar). In the absence of a quantitative result the correct interpretation is based on the majority percentage of responses from participants.

Qualitative Report

Lab Code: AE Section: 2TB2

Qualitative HCG (High Sensitivity) Results

Lab Code	Section	Method	Instrument	Sample Number			Sample Score			Average Score
				1	2	3	1	2	3	(Average)
AE	2TB2	Unipath	Clearview HCG (3min)	Negative	Negative	Positive	0	2	0	1.00
Interpretation				Negative	Wk Positive	Positive				
Spiked Value				Urine from non pregnant donor	Pregnant donor urine diluted to approx 29iu	Pregnant donor urine diluted to approx 336iu				

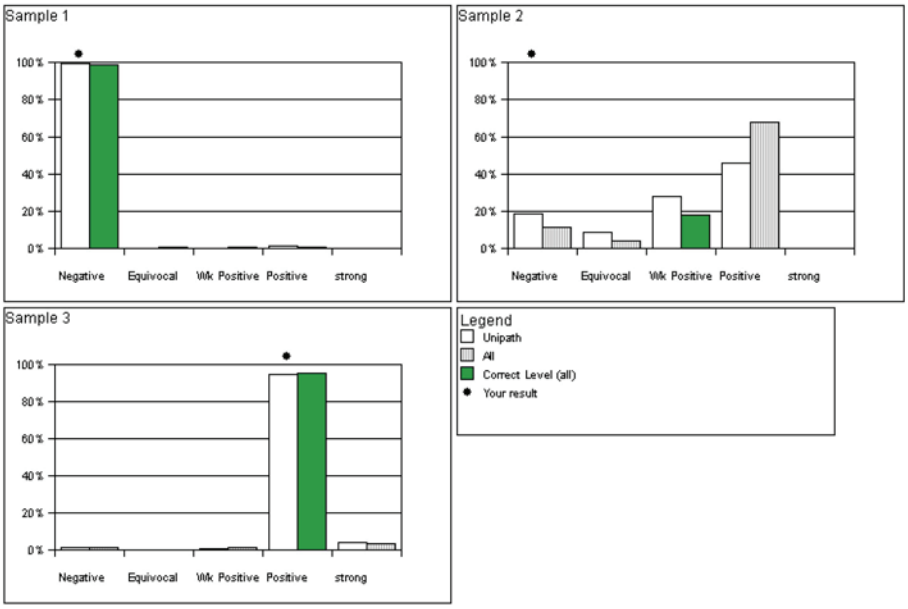


Figure 17 - Example of kit summary page - available with every distribution.

Qualitative Report

Distribution W68

Qualitative HCG (High Sensitivity) Results

Method="Unipath" Show all methods

Lab Code	Section	Instrument	Sample Number			Sample Score			Average Score
			1	2	3	1	2	3	(Average)
IU	Clinical Pathology	Clearview HCG (5min)	Negative	Equivocal,Borderline	Positive	0	1	0	0.50
ABE	Clearview EasyHCG	Clearview Easy HCG	Negative	Wk Positive	strong positive	0	0	0	0.00
ADL	EASY hCG IV502575	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	A&E UCH	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	**AAU UCH**	**Clearview Easy HCG**	**Negative**	**Negative**	**Negative**	**0**	**2**	**3**	**2.50**
JO	Archway Sexual Health	Clearview Easy HCG							
JO	Basil Samuel OP NHNN	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	Cardiac Catheter	Clearview Easy HCG							
JO	Clin Biochem	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	Clinic K UCH	Clearview Easy HCG							
JO	Clinical Research UCH	Clearview Easy HCG	Positive	Negative	Positive	2	2	0	1.33
JO	Day Surgery	Clearview Easy HCG	Negative	Negative	Positive	0	2	0	1.00
JO	Diagnostic Gynae Unit	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	EGA Breast Clinic	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	EGA Repro Med Unit	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	Hyperacute Stroke Unit UCH	Clearview Easy HCG							
JO	Lady Ann Alerton NHNN	Clearview Easy HCG							
JO	Mortimer Market Centre	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	MRI unit, NHNN	Clearview Easy HCG	Negative	Wk Positive	Positive	0	0	0	0.00
JO	National Day Care RLHH	Clearview Easy HCG	Negative	Negative	Positive	0	2	0	1.00
JO	Nuclear Medicine	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	Nutfield Ward NHNN	Clearview Easy HCG							
JO	Onco/Chemo	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	OP HTD	Clearview Easy HCG	Negative	Wk Positive	Positive	0	0	0	0.00
JO	OPD Derm 5th Fl	Clearview Easy HCG							
JO	POPD EGA	Clearview Easy HCG	Negative	Positive	Positive	0	0	0	0.00
JO	T10	Clearview Easy HCG							
GU	Rapid Assessment Unit	Clearview HCG (3min)							
GU	Samaritan OPD	Clearview HCG (3min)							
GU	Samaritan Ward	Clearview HCG (3min)							
GU	Surgery	Clearview HCG (3min)							
GU	Urogynaecology	Clearview HCG (3min)							
GU	Winsland 1st Floor	Clearview HCG (3min)							
IM	A+E Garrick	Clearview HCG (3min)	Negative	Negative	Positive	0	2	0	1.00
IM	HCG/main lab	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
IM	POCT 1	Clearview HCG (3min)							
IM	POCT 2	Clearview HCG (3min)							
IM	POCT 3	Clearview HCG (3min)							
IM	POCT 4	Clearview HCG (3min)							
IM	POCT 5	Clearview HCG (3min)							
IM	Satellite	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
MV	Haematology	Clearview HCG (3min)	Negative	Equivocal,Borderline	Positive	0	1	0	0.50
ML	Pregnancy	Clearview HCG (3min)	Negative	Equivocal,Borderline	Positive	0	1	0	0.50
MO	HCG	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
MP	Pregnancy	Clearview HCG (3min)	Negative	Negative	Positive	0	2	0	1.00
MS	Elland Ward (First Floor)	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
MS	Leeds Daycare	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
MS	Leeds Ward 2	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
MS	Longland (Methley Ward)	Clearview HCG (3min)	Negative	Negative	Positive	0	2	0	1.00
MS	Methley Ward	Clearview HCG (3min)	Negative	Wk Positive	Positive	0	0	0	0.00
MU	Pregnancy	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
NN	Pregnancy	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
OM	microbiology / pregnancy	Clearview HCG (3min)							
SP	Casualty (Clearview)	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
SP	Laboratory (Clearview)	Clearview HCG (3min)	Negative	Positive	Positive	0	0	0	0.00
VK	Pregnancy	Clearview HCG (3min)	Negative	Equivocal,Borderline	Positive	0	1	0	0.50
YH	Pregnancy	Clearview HCG (3min)	Negative	Wk Positive	Positive	0	0	0	0.00
YN	MICROBIOLOGY PREG	Clearview HCG (3min)	Negative	Wk Positive	Positive	0	0	0	0.00
ABE	TestPack 505798	Test Pack	Negative	Wk Positive	strong positive	0	0	0	0.00
ABE	TestPack 505805	Test Pack	Negative	Wk Positive	strong positive	0	0	0	0.00
Interpretation			**Negative**	**Wk Positive**	**Positive**				
Spiked Value			**Urine from non pregnant donor**	**Pregnant donor urine diluted to approx 29iu**	**Pregnant donor urine diluted to approx 336iu**				

INTERPRETATION OF EQA REPORTS - INTERACTIVE (weqas.com)

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