

Weqas GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE



INTERPRETATION OF LABORATORY EQA REPORTS





Contents

1 Statistical Analysis - Quantitative Programmes	4
1.1 Target Value Assignment and Traceability	5
1.1.1 Reference Values	5
1.1.2 Uncertainty	5
1.2 Comparability Factors	5
1.3 Scoring System	6
1.4 Performance Criteria	7
1.5 Minimum Analytical Performance Standards (MAPS)	8
1.6 The Weqas Report	10
1.6.1 Measurements of Imprecision	11
1.6.2 Measurements of Inaccuracy	12
1.6.3 Bias Plots	13
1.7 Problem Solving	. 16
1.8 Other Reports	23
2 Statistical Analysis - Qualitative Programmes	28
2.1 Target Value Assignment	28
2.2 Scoring System	. 28
2.3 The Weqas Report	29

1. Statistical Analysis - Quantitative Programmes

THE FOLLOWING APPLIES TO ALL LABORATORY PROGRAMMES AND THE POCT PROGRAMMES LISTED IN THE FOLLOWING TABLES. POCT PROGRAMMES NOT LISTED ARE COVERED IN A SEPARATE DOCUMENT. QUALITATIVE PROGRAMMES ARE COVERED IN SECTION 2.

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
Bilirubin	
Lipid	
ED Toxicology	Whole Blood Ethanol. *Ethylene Glycol and Methanol.
Serum Indices	
Blood Gas and Co-oximetry	Haematocrit. Oxygen saturation and calculated parameters. b123 Co-oximetry.
HbA1c	
Ammonia	
Endocrine	Macroprolactin
Haemantinics	Iron overload
Cardiac Marker	Semi-Quantitative
BNP and NT pro BNP	
Homocysteine	
Bile Acids	
Urine Chemistry	Acidified samples for Ca, Mg and Phosphate
Urine Oxalate and Citrate	
Serum hCG	Qualitative and Quantitative Serum hCG
Porphyrin	Includes Quantitative and Qualitative Urine, plasma, faeces and clinical cases
Serum ACE	
CRP	Includes hsCRP
TDM	
Whole Blood Immunosuppressants	
Drugs of Abuse	
Quantitative Faecal Hb	
pH Meter	
Procalcitonin	

Table 2 - POCT Programmes

Weqas Programme Title	Additional Sub Programmes / Comments	
Pregnancy Testing	Qualitative Urine and Serum Programmes	
Blood Gas / Co-oximetry	Offered with simplified reports in Lab Programme	
Bilirubin	Offered with simplified reports in Lab Programme for Bilirubinometer / Blood Gas	
	analysers	
POCT HbA1c	Bimonthly Programme offered with simplified reports in Lab Programme	
POCT Cardiac Marker	Plasma CM available for Triage meters	
	Serum CM available for other POCT devices as part of Lab Scheme	
POCT HIV		
Pre Term Labour Markers	Foetal fibronectin. Phosphorylated IGFBP-1. IGFBP-1.	
POCT BNP	Plasma BNP available for Triage meters	
POCT Creatinine		
Drugs of Abuse	Offered with simplified reports in Lab Programme	
POCT CRP		
POCT Hb		
POCT INR		

⁺ Pilot (Not Accredited)

1.1 Target value assignment and Traceability

Statistical methods that are robust to outliers complying with 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 = $\sqrt{\{(Usample)^2 + (USRM)^2\}}$

Where

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

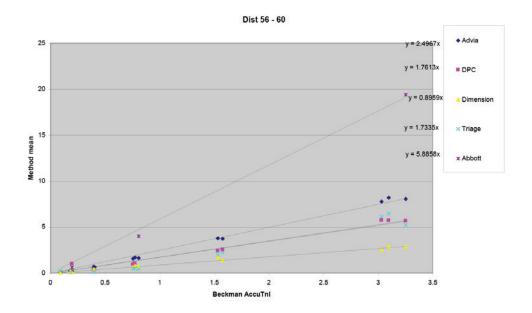
An estimate of the uncertainty of the Robust mean is calculated from:

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

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 - Inter	pretation of	Scoring	System	Based	on SD Index
--	-----------------	--------------	---------	--------	-------	-------------

less than 1	ess 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.

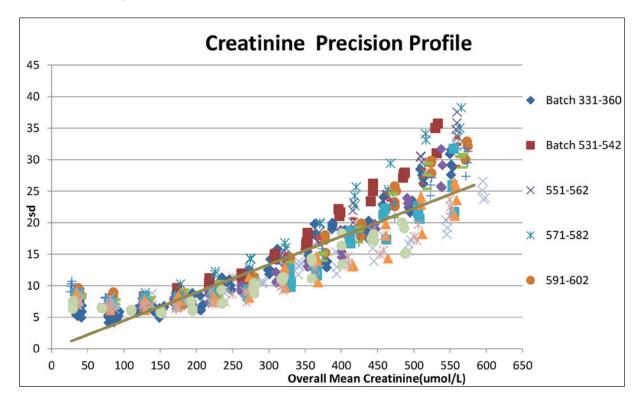


Figure 2 - Precision profile for Serum Creatinine

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 <u>https://biologicalvariation.eu/</u>

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).

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 MAI	PS, TE = (1.65*im)	orecision)+i	naccuracy	·		

Table 6 - MAPS Phase 1 Analytes

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

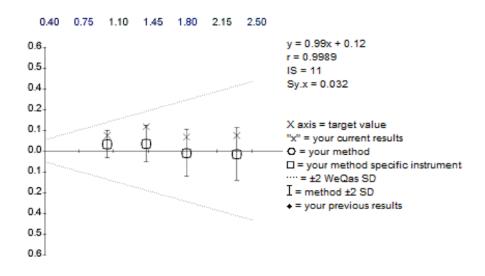
Weqas has combined the MAPS specifications into a single score called the Sigma Score.

Where $\mathsf{TE}_{\mathsf{map}}$ 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, $S_{yx} = 0.032 \text{ mmol/L}$ 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 difference 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	nt This is used as an index of within run imprecision, the wider the deviation from 1.0 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.

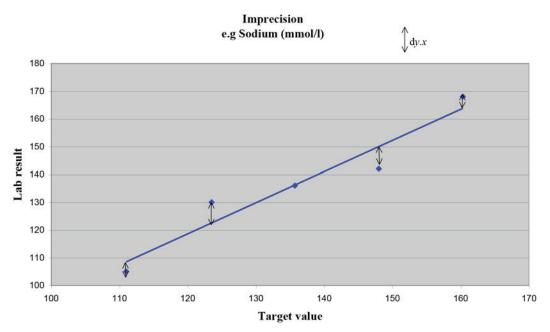
• Standard Deviation of the Residuals (Sy.x)

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





Target	Lab result	Line of fit	Deviation	Dev ²
x	y	$\tilde{\mathcal{Y}}$	$dy.x = y - \tilde{y}$	$dy.x^2$
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	$\sum dy.x$	$\sum dy.x^2$
	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:

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

• 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:

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

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 " \Box " 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



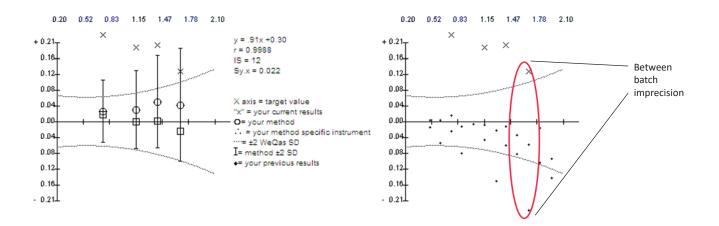


Figure 6a

Standard Report Format - Easy to read cumulative reports

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.



veqas

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

	3 -								_	All S	SDI R
36 52										< 1	Goo
52	2 -						~	_	_	1 - 2	Acc
21	1 -					\sim		~		> 2	Poo
								a			
	0 1	L358	L359	L360	L361 Distribi		L363	L364			

.... Median ---- Lab SDI ----- 97.5th

Section SDI scores for this distribution

Section	Section Harris (700)			
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		



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

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

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

Hierarchy of target values

- 1 Reference method (if available for all samples)
- 2 Method mean (if n > 8)
- 3 Overall mean

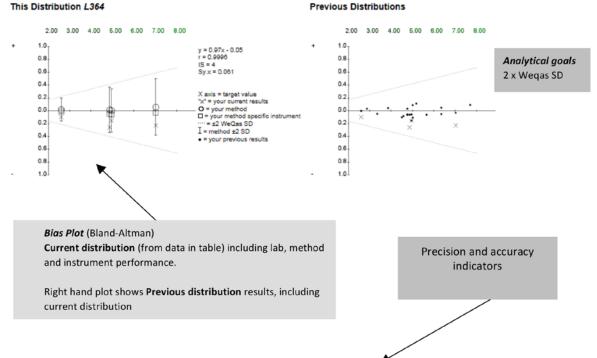
Figure 6b

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.

		I. Distribu					
Distribution D	ate: 26/0	3/18. Fina	I. Report	Issued: 20	0/04/18		
Cholesterol (mmo	I/I)	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		Total Error
Cholesterol oxidase	Mean	7.092	2.617	4.876	4.963	1	Total Ellor
	SD	0.225	0.093	0.183	0.169]	SDI is a measurement of your total error and will include both inaccuracy and imprecisio
	Number	174	174	174	174]	
	Uncert.	0.0214	0.0088	0.0174	0.0161]	This Distribution L364
Cobas C Module	Mean	7.006	2.587	4.811	4.901]	Your average analyte SDI for the 4 samples is 0.95
	SD	0.123	0.075	0.112	0.106		Four average analyte SDF for the 4 samples is 0.95
	Number	98	98	98	98]	Previous SDI
	Uncert.	0.0155	0.0094	0.0142	0.0134]	
Overall	Mean	7.081	2.615	4.868	4.953	1	Distribution L364
	SD	0.233	0.090	0.189	0.174]	
	Number	179	181	179	181		3 -
	Uncert.	0.0218	0.0084	0.0176	0.0161		
Reference Values CDC		7.038	2.606	4.867	4.963		2
Ref. Value Uncertainty		0.0140	0.0000	0.0000	0.0000	1	
Non-scoring Reference Values ID-GCMS		7.110	2.590	4.850	4.970	1	0 L366 L359 L360 L361 L362 L363 L364 Distribution
WeQas SD		0.301	0.111	0.207	0.210	1	Company of the second sec
SDI		-0.79	-0.95	-1.29	-0.77	0.95	
	5	igma Met	rics				Median Your SDI 97.5th
	Critica	Level 1: 5	.0 mmol/l				
Minimum Acceptable score		Critical Le	vel 1 Sign	na score		3.8	
MAPS Allowable TE	8.5%						Sigma Score using
MAPS Allowable bias %		Lab bias				3.9%	
MAPS Allowable CV %	2.7%	Lab CV %)			1.2%	MAPS criteria.
Please note: Linear regression u	ses CF co	prrected da	ita.				

This Distribution L364



Precision

This Distribution L364	Previous Distributions	L363	L362	L361	L360	L359	L358
$S_{V} x = 0.061 \text{ mmol/l}$	Sy.x	0.046	0.092	0.098	0.058	0.074	0.034
Sy.x = 0.061 mmol/l IS = 4	15	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 \pm 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.

		Type of Error					
	Imprecision	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		

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

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.

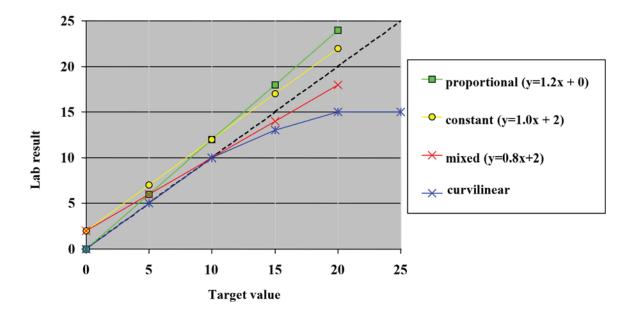
Is it Inaccuracy?

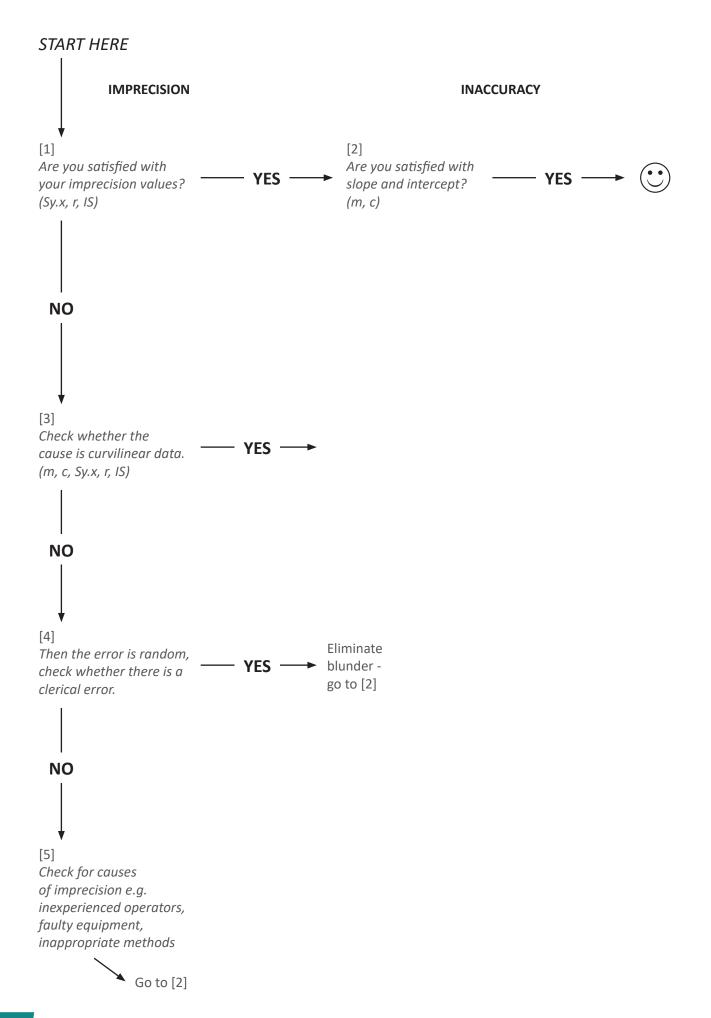
Inaccuracy can be due to:

- 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.







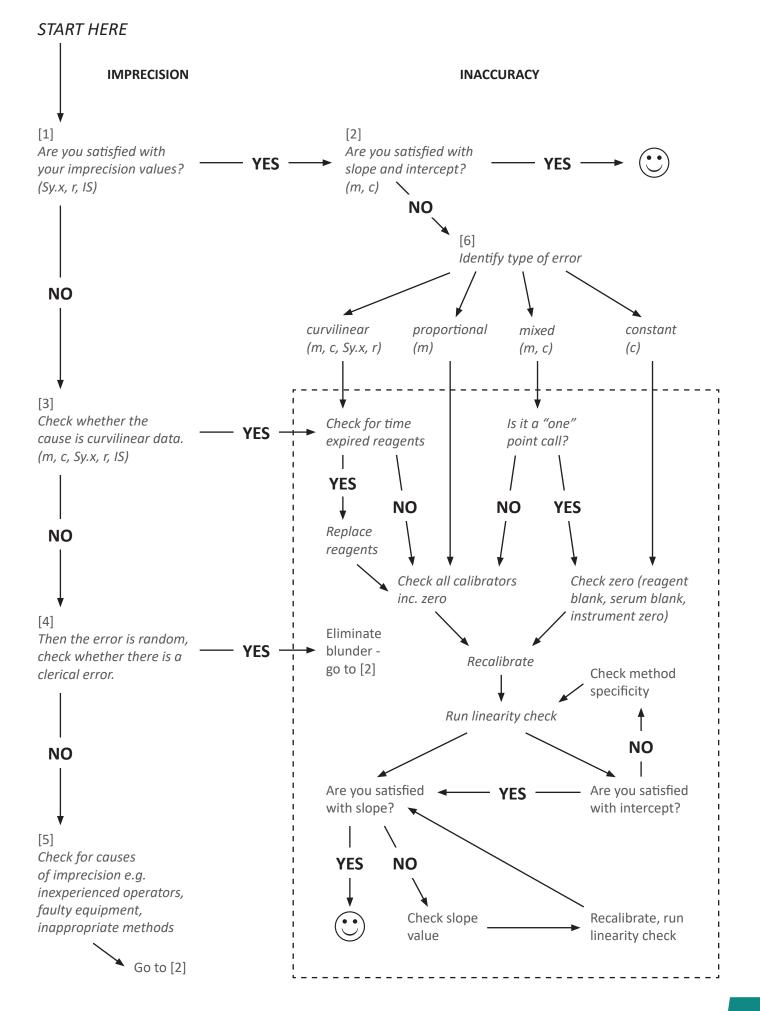


Figure 9a - Bias Plot - With Explanation

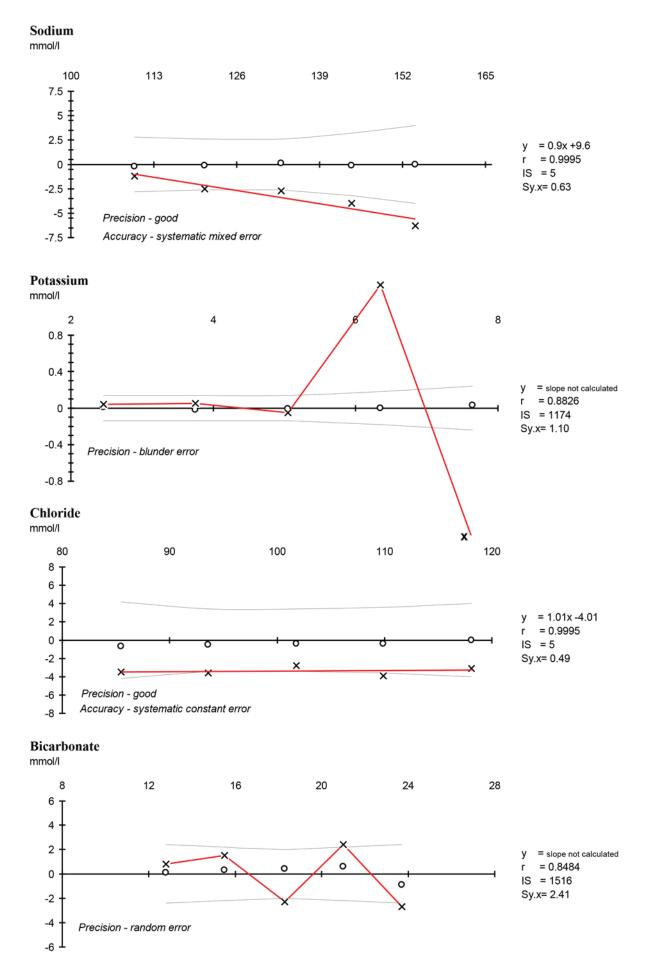
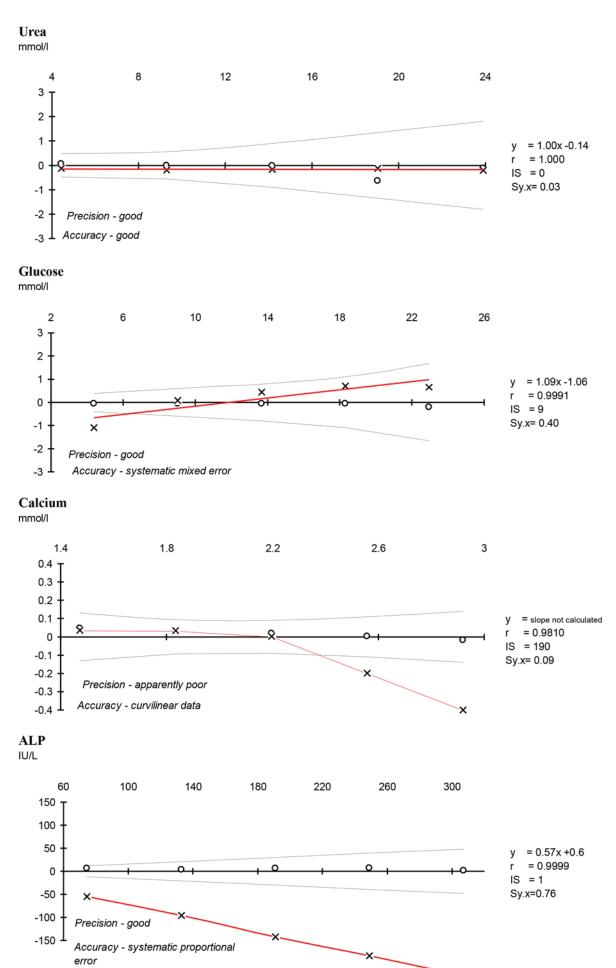


Figure 9b - Bias Plot - With Explanation



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 curvilinearError randomCause 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.wegas.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 Co	de : Ol	Sent	on: 1/08	/11
Magnesium (mm	ol/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
СН		1.79	1.63	0.46	1.18
сн		1.79	1.64	0.50	1.20
СН		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
кн		1.81	1.66	0.51	1.21
кн		1.73	1.61	0.50	1.18
кJ		1.72	1.58	0.44	1.18
кJ		1.72	1.59	0.50	1.19
кк		1.80	1.66	1.21 *	
кк		1.80	1.64	0.49	1.20
кк		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 R	d - Outside Range.*	Instrum	ent Ort	ier	

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.

Distribution: Distribution Date: Analyte:	QH 02-Nov-15 Creatinine (µmol/L)	Weqa	IS			
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

Mainline Chemistry Summary Sheet Distribution QH

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.

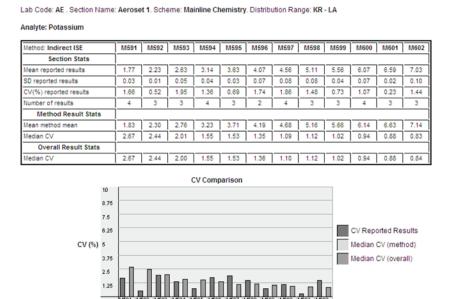


Figure 13 - Regional / Network reports

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.

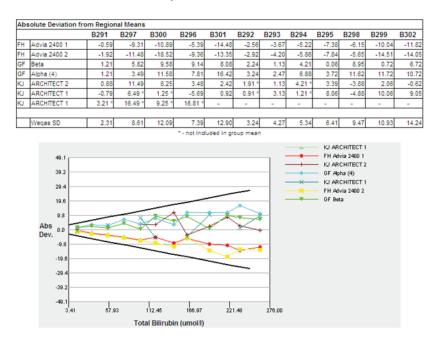
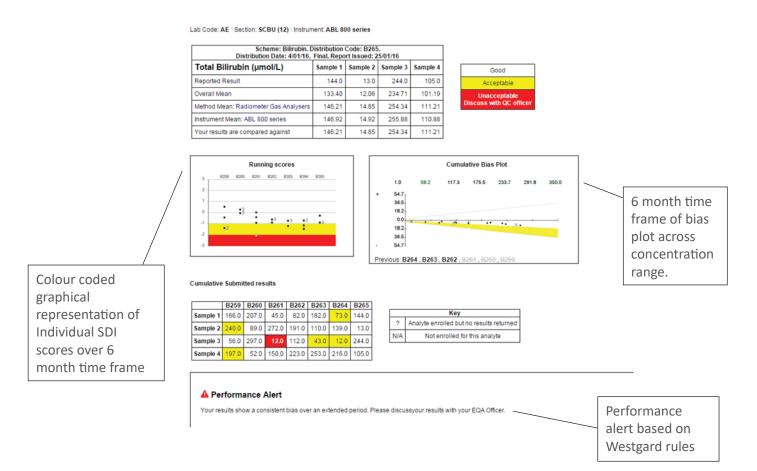
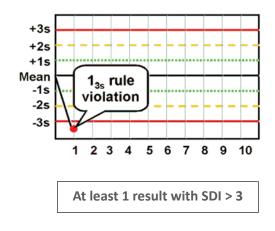


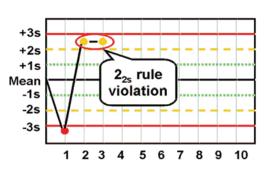
Figure 14 - Simplified Reports

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.



The following rules are used for the Performance alert.





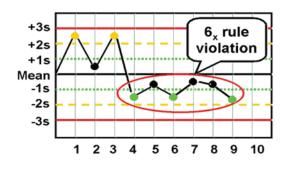
At least 2 results with SDI > 2

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.

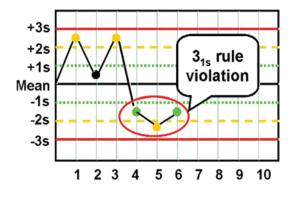
This is calculated over several distributions and will depend on the number of samples distributed per round e.g. if 3 samples are distributed per round, then the rule will be calculated over 2 distributions.



# 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 <i>or</i> 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 <u>individual</u> <u>score</u> is:

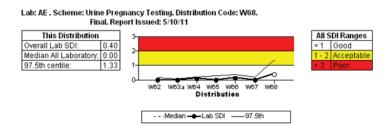
Score	Interpretation
0	Good
1	Acceptable
2	Warning
> 2	Unacceptable

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

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)	<u>1.00 (avq)</u>	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>	2	2	2	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>	2	
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)	<u>0.00 (avq)</u>	<u>1.00 (avg)</u>	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>	2	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>	

SDI Code	Meaning	Please note: Method and Instrument Summary reports a	re available to download				
N/A	Not enrolled for this analyte	via the 'Lab Stats' or 'Section Stats' menu.					
?	Analyte enrolled but no results returned						
N/S	This analyte not scored	If you don't currently have interactive access , please con	tact WEOAS for a				
**	SDI score greater than 2	registration form on 02920 314750.	act we also for a				
		registration form of 02020 of 4100.					

	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 diluter 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.

Comments:

Figure 16 - Individual Selection Report

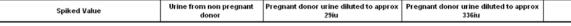
The individual section report includes a graphical representation of the participant's results compared with other participants using the same method (white bar), results for all methods (grey bar) and the correct interpretation based on the quantitative result (green bar). In the absence of a quantitative 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				ampl Score		Average Score
				1	2	3	1	2	3	(Average)
AE	2TB2	<u>Unipath</u>	Clearview HCG (3min)	Negative	Negative	Positive		2	0	1.00
Interpretation Negative		Wk Positive	Positive							



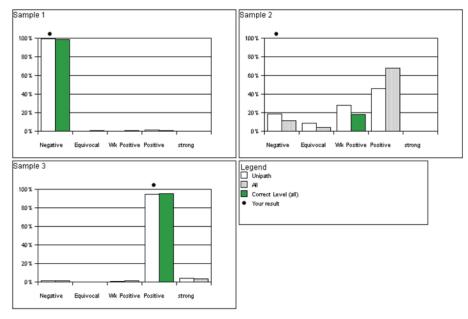


Figure 17 - Example of kit summary page - available with every distribution.

Qualitative Report

Distribution W68

Qualitative HCG (High Sensitivity) Results

Method="Unipath" Show all methods



Lab Code Average Score Sample Score Section Instrument Sample Number 1 2 3 1 2 3 (Average) 0 1 0 IU Clinical Pathology Clearview HCG (5min) Negative Equivocal,Borderline Positive 0.50 0 0 0 ABE Wk Positive 0.00 Clearview EasyHCG strong positive Clearview Easy HCG Negative 0 0 0 ADL EASY hCG IV502575 Positive 0.00 Negative Positive Clearview Easy HCG ASE UCH JO Positive Positive 0 0 0 0.00 Negative Clearview Easy HCG JO AAU UCH llegative 0 2 3 2.50 Clearview Easy HCG Negative Negative JO Archway Sexual Health Clearview Easy HCG 0 0 0 JO Basil Samuel OP NHNN Clearview Easy HCG Negative Positive Positive 0.00 JO Cardiac Catheter Clearview Easy HCG JO Clin Biocherr Positive Positive 0 0 0 0.00 Negative Clearview Easy HCG JO Clinic K UCH Clearview Easy HCG 2 2 0 JO Clinical Research UCH Positive Positive 1.33 Clearview Easy HCG Negative Day Surgery JO Negative Positive 0 2 0 1.00 Clearview Easy HCG Negative 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 0 0 0 JO 0.00 EGA Repro Med Unit Clearview Easy HCG Negative Positive Positive JO Hyperacute Stroke Unit UCH Clearview Easy HCG JO Lady Ann Alerton NHNN Clearview Easy HCG JO Mortimer Market Centre Negative Positive Positive 0 0 0 0.00 Clearview Easy HCG JO MRI unit, NHNN Clearview Easy HCG Negative Wk Positive Positive 0 0 0 0.00 0 2 0 JO National Day Care RLHH Clearview Easy HCG Negative Negative Positive 1.00 JO Nuclear Medicine Clearview Easy HCG Negative Positive Positive 0 0 0 0.00 JO Nuffield Ward NHNN Clearview Easy HCG 0 0 0 JO Onco/Chemo Negative Positive Positive 0.00 Clearview Easy HCG JO OP HTD 0 0 0 Negative Wk Positive Positive 0.00 Clearview Easy HCG JO OPD Derm 5th FI Clearview Easy HCG JO POPD EGA Negative Positive Positive 0 0 0 0.00 Clearview Easy HCG 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 Clearview HCG (3min) Surgery Clearview HCG (3min) GU Urogyna GU Winsland 1st Floor Clearview HCG (3min) 0 2 0 1.00 IM A+E Garrick Clearview HCG (3min) Negative Negative Positive IM 0 0 0 HCG/main lab Negative Positive 0.00 Clearview HCG (3min) Positive м POCT 1 Clearview HCG (3min) M POCT 2 Clearview HCG (3min) IM POCT 3 Clearview HCG (3min) M POCT 4 Clearview HCG (3min) IM POCT 5 Clearview HCG (3min) 0 0 0 IM 0.00 Positive Positive Satellite Clearview HCG (3min) Negative W Haematology Equivocal,Borderline Positive 0 1 0 0.50 Negative Clearview HCG (3min) 0 1 0 0.50 ML Pregnancy Negative Equivocal,Borderline Positive Clearview HCG (3min) MO HCG Clearview HCG (3min) Negative Positive Positive 0 0 0 0.00 MP Pregnancy Negative Negative Positive 0 2 0 1.00 Clearview HCG (3min) MS Elland Ward (First Floor) Clearview HCG (3min) Negative Positive Positive 0 0 0 0.00 MS 0 0 0 0.00 Leeds Daycare Clearview HCG (3min) Negative Positive Positive 0 0 0 MS 0.00 Positive Positive Leeds Ward 2 Clearview HCG (3min) Negative 0 2 0 MS Longland (Methley Ward) Clearview HCG (3min) Negative Negative Positive 1.00 MS Wk Positive Positive 0 0 0 0.00 Methley Ward Clearview HCG (3min) Negative Pregnancy Negative MU Clearview HCG (3min) 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) 0 0 0 SP 0.00 Casualty (Clearview) Positive Positive Clearview HCG (3min) Negative SP Positive 0 0 0 0.00 Laboratory (Clearview) Clearview HCG (3min) Positive Negative VK Equivocal,Borderline 0 0.50 Pregnancy Negative Positive 0 1 Clearview HCG (3min) YH Pregn Wk Positive Positive 0 0 0 0.00 Clearview HCG (3min) Negati 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 0 0 0 0.00 TestPack 505805 Test Pack Negative Wk Positive strong positive Interpretation Negative Wk Positive Positive t donor urine diluted to approx 336iu Urine from non pregna donor Pregnan donor urine diluted to approx 29iu Pregnan Spiked Value





INTERPRETATION OF LABORATORY EQA REPORTS

Weqas



+44 (0)2920 314750

+44 (0)2920 314760

contact@weqas.com



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





