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

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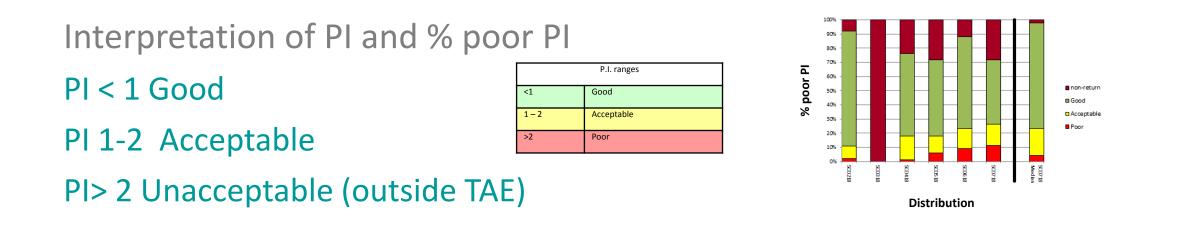
Annette Thomas



- Weqas SDs have been replaced by TAE (Total Allowable Error).
- This provides a better description of the Analytical performance specification as these are not based on the SD of the distribution, (Clinically relevant criteria/ biological variation/ state of the art).
- Performance specification limits = target value ± TAE
- SDI has been replaced by PI (Performance Index)
- PI = (your result target value) (TAE/2)



### Poor performance monitoring



Overall Laboratory SDI has been replaced by % poor PI as the overall performance index. This represents the proportion of tests which obtained a poor score or were not returned

e.g. you measured 30 analytes on 3 samples on 2 instruments (180 tests) and had 5 PI scores > 2, therefore the overall % poor PI = 5/180 = 2.8%. Provides equal weighting for all the samples rather than averaging an SDI score.



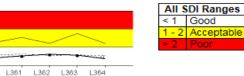
### The Reports – Manager's Summary - Quantitative

### Old

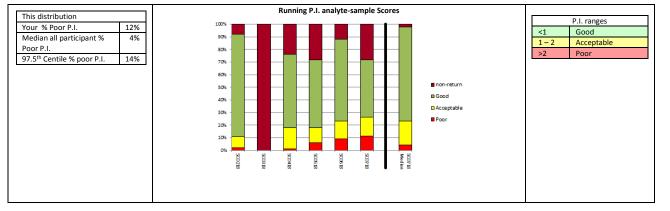
L358 L359 L360

Distribution

Median \_\_ Lab SDI \_\_\_\_ 97.5th



#### Quantitative Analyte Data



New

		P.I.	Scores		
Location	Location Name 1	Locatio	n Name 2	Location	Name 3
Instrument Name	15Character Name	15Character Name	15Character Name	15Character Name	15Character Name
Instrument Serial #	Serial#00001	Serial#00002	Serial#00003	Serial#00004	Serial#00005
analyte Name 1	NRR	NRR	0.78	N/A	5.28
analyte Name 2	NRR	NRR	0.69	1.18	5.01
analyte Name 3	NRR	NRR	0.58	1.29	4.95
analyte Name 4	NRR	NRR	0.92	1.02	4.82
analyte Name 5	NRR	NRR	0.38	1.38	5.29
analyte Name 6	NRR	NRR	0.14	1.01	6.01
analyte Name 7	NRR	NRR	0.68	0.84	4.92
analyte Name 8	NRR	NRR	0.25	0.78	5.12
analyte Name 9	NRR	NRR	0.31	N/A	4.98
analyte Name 10	NRR	NRR	0.42	N/A	5.34
Overall % poor P.I.	NRR	NRR	3.3%	9.5%	66.6%

#### Section SDI scores for this distribution

0.36

0.52

1.21

This Distribution

Overall Lab SDI:

97.5th centile:

Median All Laboratory:

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

### The Reports – Manager's Summary - Quantitative

### Group Version:

- Group report
  - Your % poor PI should be calculated based on all the tests for all the instruments in the group
  - Include a preference option for a group level user to choose whether or not to include the % poor P.I. for each of the participants within their group on this report

Version 1: user chooses not to include individual participant breakdown

This distribution	_
Your Group % Poor P.I.	3%
Median all participant % Poor P.I.	4%
97.5 <sup>th</sup> Centile % poor P.I.	14%

Version 2: users chooses to include individual participant breakdown, small number of participants in the group

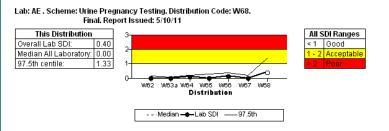
This distribution	-
Your % Poor P.I. Overall group	3%
FGA0001	2%
FGC0001	5.2%
FHA0001	3.1%
Median all participant % Poor P.I.	4%
97.5 <sup>th</sup> Centile % poor P.I.	14%

Participant code	Location	Instrument Serial #	Instrument Name	Analyte name 1	Analyte name 2	Analyte name 3	Analyte name 4	Analyte name 5	Analyte name 6	Analyte name 7	Analyte name 8	Analyte name 9	Analyte name 10	Analyte name 11	Analyte name 12	Analyte name 13	Analyte name 14	Overall % Poor P.I
		AB123456789C	Link	0.98	##.# #	##.##	##.# #	##.# #	##.# #	1.02	##.# #	##.# #	##.# #	N/A	N/A	N/A	0.98	6.1%
	A1	BC123456789D	North	1.52						1.68				N/A	N/A	N/A	0.98	12.1 %
XYZ0001			South	0.45						0.52	##.# #	##.# #	##.# #	N/A	N/A	N/A	0.98	18.1 %
×	A2 North	CD123456789E		2.58						N/A	##.# #	##.# #	##.# #	N/A	N/A	N/A	0.98	33.3 %
	A2 South	DE123456789F		?						?	##.# #	##.# #	##.# #	N/A	N/A	N/A	0.98	81.8 %
			Bed 1	?						N/A	##.# #	##.# #	##.# #	N/A	N/A	N/A	0.98	33.3 %
	A3 Link Trauma		Bed 2	?						N/A	##.# #	##.# #	##.# #	N/A	N/A	N/A	0.98	33.3 %
XXZ0001	A4 North	EF123456789G		?						?	##.# #	##.# #	##.# #	N/A	N/A	N/A	?	100 %
×	A4 South	FG123456789H		0.87						1.21	##.# #	##.# #	##.# #	N/A	N/A	N/A	0.98	21.2 %
	A5 North (H&N/ENT)	GH123456789I		0.25	28.4 5					0.28	##.# #	##.# #	##.# #	N/A	N/A	N/A	2.98	15.1 %
ZZZ0001	Outpatients department		Clinic 1	##.##	##.# #	##.##	##.# #	##.# #	##.# #	##.# #	##.##	18.2 %						

### Manager's Summary - Qualitative

#### Weqas

Unit 6, Parc Ty Glas Llanishen, Cardiff CF14 5DU 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 (avg)</u>	<u>1.00 (avq)</u>	<u>0.00 (avq)</u>	0.00 (avg)	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>	2	<u>0.00 (avq)</u>	<u>0.00 (avq)</u>

How do we calculate the % poor PI?

% of how many samples you misclassified as a total % of all samples assayed.

#### % poor PI = % incorrect results

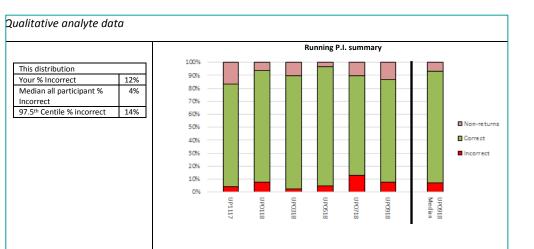
Old

office@weqas.com

Scheme Organiser:

Annette Thomas

### New



						Ana	yte Na	me 1	Analyte Name 2			Ana	yte Nar	ne 3	Ana	yte Na	me 4	Anal	yte Nai	me 5
		Participant	Location	Instrument Name	Serial number	Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3
	Correct Qualitative response Incorrect Qualitative response	AAA001	Location Name 1		SN0000001	Neg	Pos	Pos	Pos	Neg	Pos	Pos	Neg	Pos	Neg	Pos	Pos	Pos	Pos	Neg
N/A	Aualitative Performance not assessed Not enrolled for this analyte	AAA001	Location Name 2	Bay 2A	SN000002	Neg	Pos	Neg	Neg	Pos	Pos	Neg	Neg	Pos	Neg	Pos	Neg	Neg	Pos	Neg
NRR	Analyte enrolled but no results returned	AAA001	Location Name 2	Bay 2B	SN000003	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR	NRR
N/S	This quantitative analyte not scored for this distribution	AAA001	Location Name 3		SN000004	Neg	Pos	Neg	Equ	Equ	Neg	N/A	N/A	N/A	Neg	Pos	Neg	Neg	Pos	Pos
NNR	Non-numerical results submitted: P.I. not available	AAA001	Location Name 3		SN0000005	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Pos	Neg	Pos	Neg	Pos	Pos	Bor

### The Reports – Analyte Report - Quantitative

### Old

Sche Distribution D		1. Distribu 3/18. Fina			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	1	Total Error
Cholesterol oxidase	Mean	7.092	2.617	4.876	4.963		Total Error
	SD	0.225	0.093	0.183	0.169	]	SDI is a measurement of your total error and will include both inaccuracy and imprecision
	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 3DF for the 4 samples is 0.53
	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	]	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		2
Reference Values CDC		7.038	2.606	4.867	4.963		
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		L358 L359 L360 L361 L362 L363 L364
WeQas SD		0.301	0.111	0.207	0.210	1	2 DIM NOR Y
SDI		-0.79	-0.95	-1.29	-0.77	0.95	
	5	igma Met	rics				Median Your SDI 97.5th
	Critical	Level 1: 5	.0 mmol/l				
Minimum Acceptable score		Critical Le	evel 1 Sign	na score		3.8	
MAPS Allowable TE	8.5%						
MAPS Allowable bias %		Lab bias				3.9%	
MAPS Allowable CV %	2.7%	Lab CV %				1.2%	
lease note: Linear regression u	ises CF co	prrected da	ata.				

Coheman Linial Distribution Codes 1904

This Distribution L364

2.00 3.00 4.00 5.00 6.00 7.00 8.00



Previous Distributions

1.0<sub>T</sub>

0.8

0.6

04

0.2

0.0

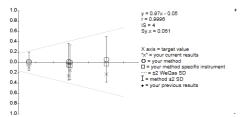
0.2

0.4

0.6

0.8.

1.0



#### Precision

#### Precision Key

0									
Sy.x = 0.061 mmol/l Sy.x	.x	0.046	0.092	0.098	0.058	0.074	0.034	0 to 10	Good
IS = 4 IS		6	9	11	6	11	3	11 to 150 > 150	Acceptable to Warning level Unacceptable (including Curvilinear Data)

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

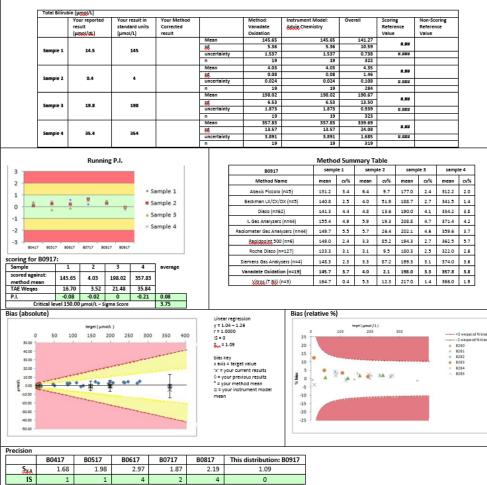
#### Accuracy

This Distribution L364	<b>Previous Distributions</b>	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.

### New

Participant Code: BY00001 · Location: <###20 Characters##> Analyser Name: <15 Characters> · Serial #: AB00045237A Scheme: Bilirubin. Distribution Code: 80917. Analyte: Total Bilirubin Distribution start: 04-Sep-17 Distribution End: 18-Sep-2017 Report Issued: 22-Sep-2017 Report Status: final



Syx is the average deviation from the best fit line and is an index of scatter

	Your reported result (µmol/dL)	Your result in standard units (µmol/L)	Your Method Corrected result		Method: <u>Vanadate</u> <u>Oxidation</u>	Instrument Model: <u>Advia</u> <u>Chemistry</u>	Overall	Scoring Reference Value	Non- Scoring Reference Value
				Mean	145.65	145.65	141.27	<u>и</u> пп	
C				sd	5.36	5.36	10.59	#.##	
Sample 1	14.5	145		U	1.537	1.537	0.738	#.###	
				n	19	19	322		
				Mean	4.03	4.03	4.35	<u>и</u> пп	
C				sd	0.08	0.08	1.46	#.##	
Sample 2	0.4	4		U	0.024	0.024	0.108	#.###	
				n	19	19	284		
				Mean	198.02	198.02	190.67		
	100	400		sd	6.53	6.53	13.50	#.##	
Sample 3	19.8	198		U	1.873	1.873	0.939	#.###	
				n	19	19	323		
				Mean	357.83	357.83	339.69		
6	25.4	254		sd	13.57	13.57	24.08	#.##	
Sample 4	35.4	354		U	3.891	3.891	1.685	#.###	
				n	19	19	319		

Results displayed in your units, can directly compare results across the columns for lab, method, instrument, overall and reference method.

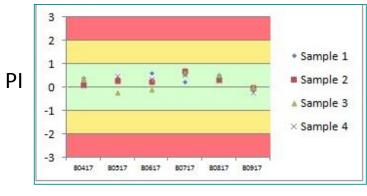
## Method Summary Table – top 10 methods displayed

B0917	samp	le 1	samp	ole 2	samp	le 3	samp	le 4
Method Name	mean	cv%	mean	cv%	mean	cv%	mean	cv%
Abaxis Piccolo (n=5)	131.2	3.4	6.4	9.7	177.0	2.4	312.2	2.0
Beckman LX/CX/DX (n=5)	140.8	2.5	4.0	51.9	188.7	2.7	341.5	1.4
Diazo (n=62)	141.3	4.4	4.8	13.6	190.0	4.1	334.2	3.8
IL Gas Analysers (n=44)	155.4	4.9	5.9	19.3	208.8	4.7	371.4	4.2
Radiometer Gas Analysers								
(n=44)	149.7	5.5	5.7	26.4	202.1	4.6	359.6	3.7
Rapidpoint 500 (n=6)	149.0	2.4	3.3	85.2	194.3	2.7	362.5	5.7
Roche Diazo (n=127)	133.3	3.1	3.1	9.5	180.3	2.5	322.0	2.6
Siemens Gas Analysers								
(n=4)	148.3	2.3	3.3	87.2	199.3	3.1	374.0	3.6
Vanadate Oxidation (n=19)	145.7	3.7	4.0	2.1	198.0	3.3	357.8	3.8
Vitros (T Bil) (n=3)	164.7	0.4	5.3	12.3	217.0	1.4	366.0	1.9

- top 10 method groups ordered in terms of decreasing values of n=#
- Hyperlink allows the user to access the full method summary table listing data for all the method groups for that analyte



#### Running PI



Distribution

This plot shows the current distribution and the previous 5 distributions in which this instrument was included, in date order from left (earliest distribution) to right (most recent distribution

All the Samples are now plotted rather than just the Avg SDI

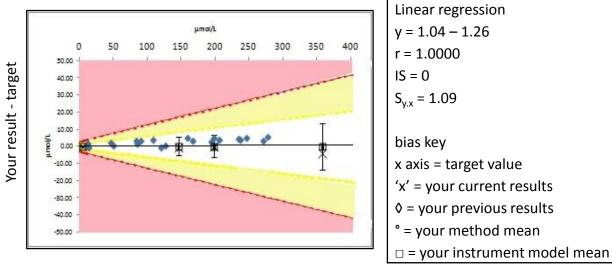
Both negative and positive PIs are displayed

#### PI Scores for this Distribution B0917

Sample	1	2	3	4	average
scored against: method mean	145.65	4.03	198.02	357.83	
TAE Weqas	16.70	3.52	21.48	35.84	
P.I.	-0.08	-0.02	0	-0.21	0.08
Critical level	3.75				

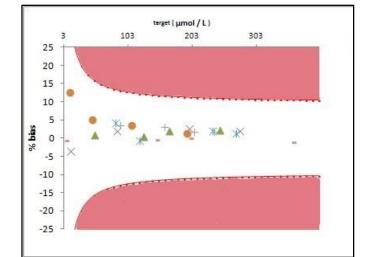
States what is being used at the target value States the performance specification limits (TAE) PI score for each sample (+ or - ) Sigma score

#### Absolute – Bias plot



Target value

#### Relative – Bias plot





Target value

Red line represents target ± TAE, yellow line represents target ± 0.5 TAE .

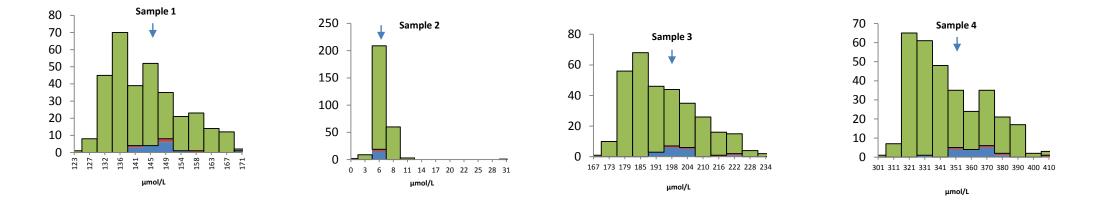
Red area represents unacceptable results, PI >2 Yellow area represents acceptable results, PI = 1-2White area represents good results, PI <1

#### Graph now includes previous results

#### Red line represents target ± TAE

Previous Distributions are highlighted as separate series

#### Histogram of results



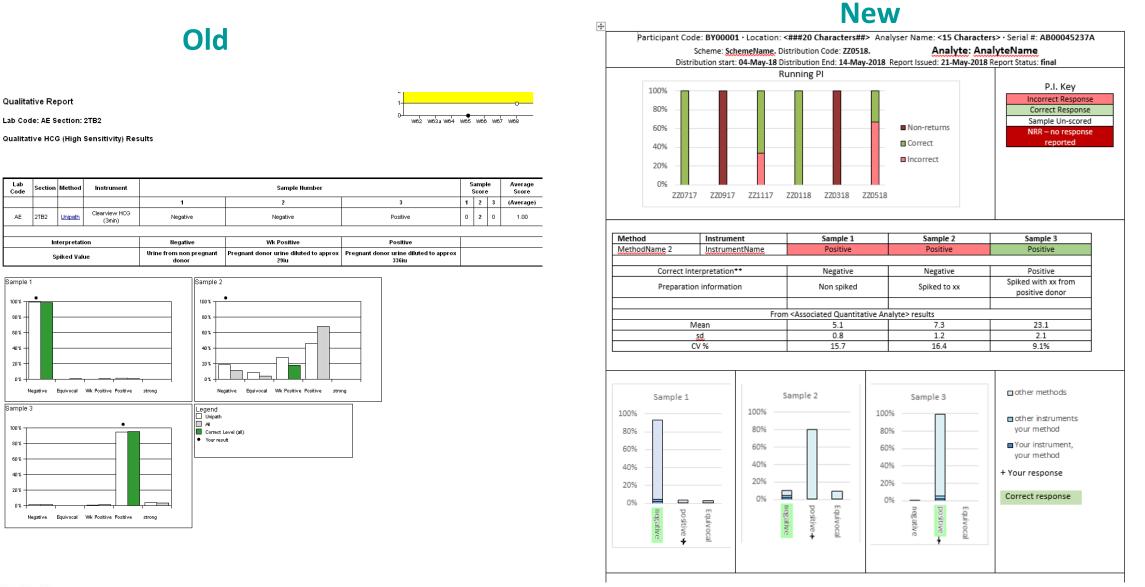
Green – all results Blue – Method Pink - Instrument

#### Comments box

Weqas supplied comment for Total Bilirubin:	Participant supplied comment for Total Bilirubin:
There is no comment for Total Bilirubin for this distribution	Calibrator Lot # BB128974.
	Awaiting engineer callout for scheduled maintenance



## The Reports – Analyte Report - Qualitative



Lab

Code

AE 2TB2

Sample 1

100%

80% -

60% -

40 % -

20 %

0%.

Sample 3

100 %

80%

60%

40 % ·

20%

0%

**Running PI** 



Similar to the manager's summary for qualitative analytes, this plot is a stacked % plot based on the performance interpretation of individual test responses for the given analyte-instrument combination across all samples.

#### Data Table

Method Instrument		Sample 1	Sample 2	Sample 3	
MethodName 2 InstrumentName		Positive	Positive	Positive	
Interpretation**		Negative	Negative	Positive	
Sample Description		Non spiked	Spiked to xx	Spiked with xx from positive donor	
	From <	Associated Quantitative A	nalyte> results		
Mean		5.1	7.3	23.1	
SD		0.8	1.2	2.1	
CV %		15.7	16.4	9.1%	

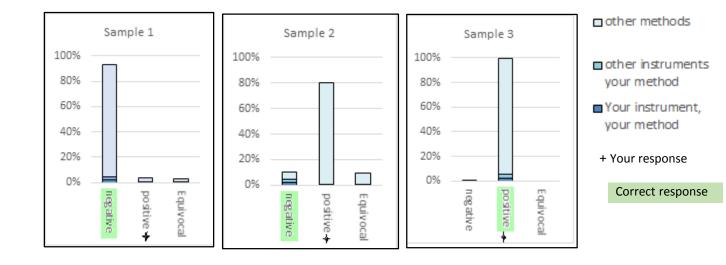
Row 1: the responses reported by the User, colour coded according to the performance classification assigned for that response.

Where no result has been submitted, NRR would be indicated and coloured red Where no performance classification has been assigned (flagged to not score) the response would appear with no coloured background applied

Row 2: The correct interpretation for that sample. Cut off for interpretation based on clinical use / outcomes

Row 3: Description of the concentration / nature of the sample

Row 4 - 7: If the qualitative analyte has been associated with a quantitative analyte in the same scheme, the table would include summary information for that analyte.



#### Method Summary Table – top 10 methods displayed

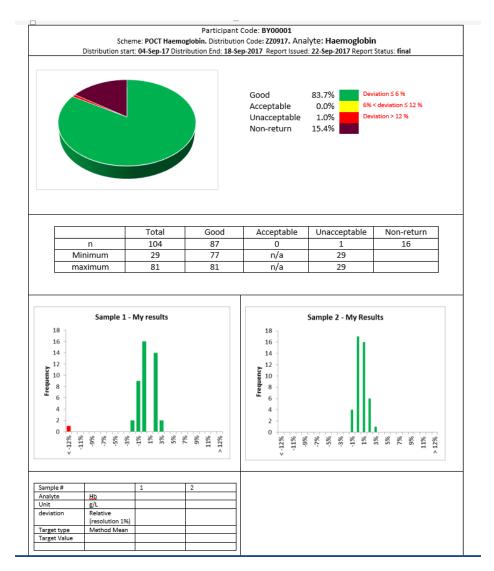
		sample 1			sample 2			sample 3		
	Detection	Negetive	Positive	Equivoca	Nesstive	Desitive	Equivoca	Negative	Desitive	Equivoca
	limit	Negative	Positive	I	Negative	Positive	1	Negative	Positive	
Method 1 (n=51)	7	48	2	1	8	27	15	0	51	0
<sup>†</sup> Method 2 (n=16)	9	14	1	1	13	1	2	0	15	0
Method 3 (n=25)	7	25	0	0	0	24	1	0	25	0
Method 4 (n=30)	6	26	1	3	1	29	0	1	29	0
Method 5 (n=97)	7	92	3	2	2	90	5	0	97	0
Method 6 (n=12)	7	12	0	0	0	12	0	0	12	0
Method 7 (n=20)	7	18	2	0	0	19	1	0	20	0
Method 8 (n=4)	7	4	0	0	1	3	0	0	4	0
Method 9 (n=34)	7	31	1	2	5	26	3	1	33	0

method group for the instrument to which this report relates is highlighted in bold.

Simpler and clearer than previous graphs

### Weqas

## POCT Manager's overview report



All the existing reports from Cuesee website will be available but with improved formatting:

Overview report with link to reagent lot no. Simplified report No-results booked Poor-performance report

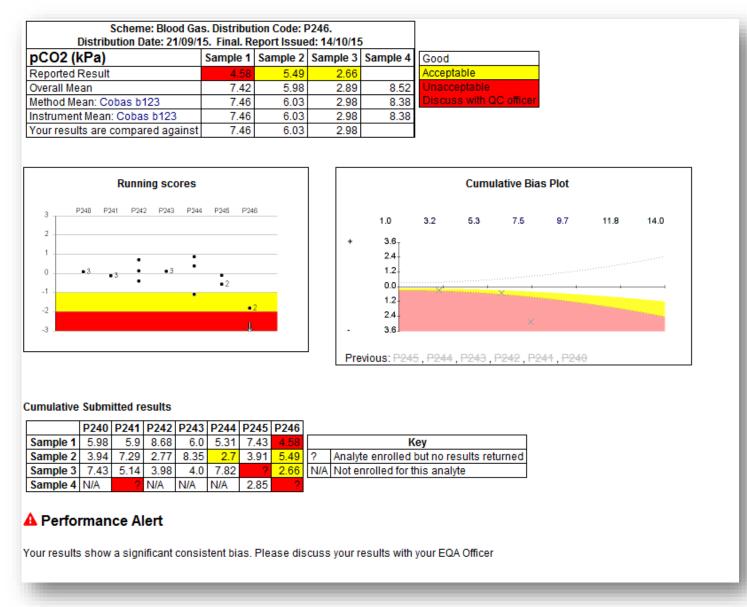
Standard letters will also be made available:

Distribution letters No results booked letter Poor performance letter

# Other improved reports

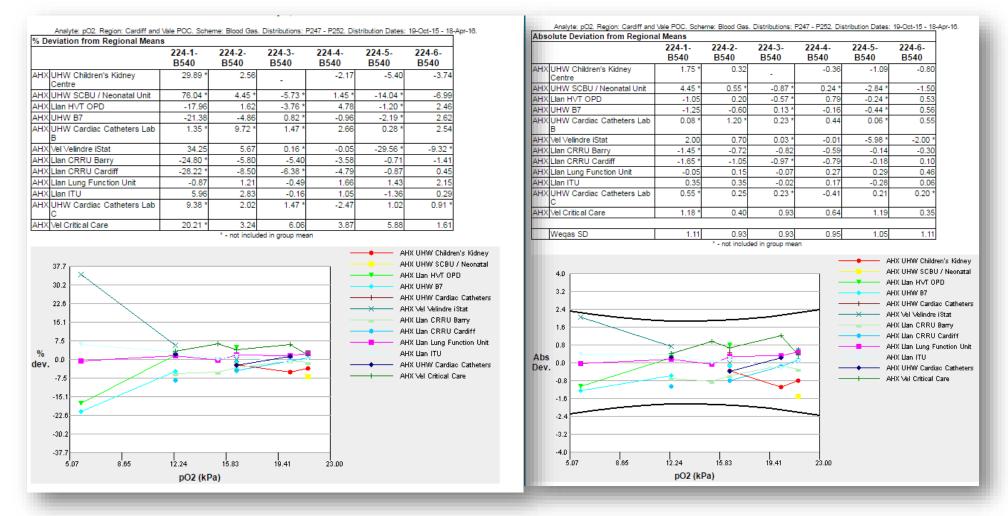


### Simplified Reports – PI scores and % poor PI added





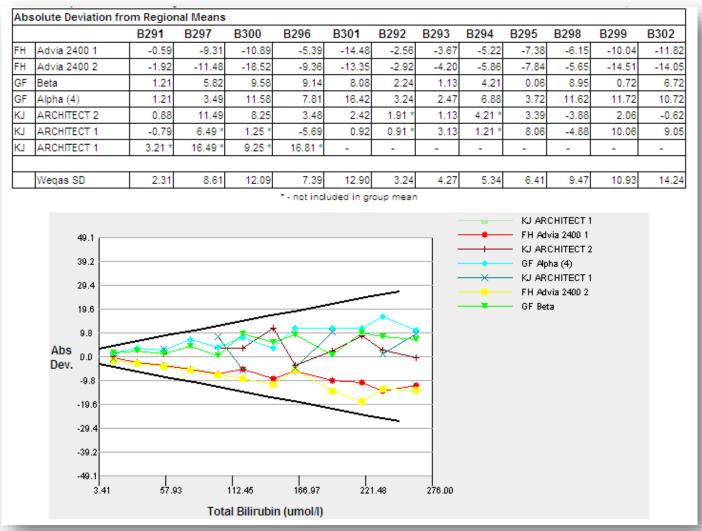
## Regional report – improved graphics.



for all instruments in the group, deviation reports provide absolute and % deviation from the group mean on a per analyte basis

Available to print from your browser, or in PDF format to your email address

## Regional report – available as a region/ group/ participant



A group can be set up as an individual lab code with multiple sections or with different lab codes and sections.

## 15189 Compliance Report

To include:

Measurement uncertainty – Between batch SD over length of batch.

Accuracy - average bias over length of batch against reference method or peer group

Traceability to high order reference method (if available)

Sigma Score where:  $\delta = (TAE - Average Bias) / between batch CV%$  Provides between batch imprecision over length of batch – 6 to 12 months for all sections.

Lab Code: AHX . Section Name: Lian CRRU Barry. Scheme: Blood Gas. Distribution Range: P247 - P252

Analyte: pCO2 (kPa)

Method: ABL 80	224-1-B540	224-2-B540	224-3-B540	224-4-B540	224-5-B540	224-6-B540
Section Stats						
Mean reported results	8.62	7.58	5.96	5.16	3.99	2.77
SD reported results	0.41	0.43	0.13	0.09	0.34	0.25
CV(%) reported results	4.79	5.67	2.26	1.78	8.55	8.94
Number of results	3	3	2	3	3	3
Method Result Stats						
Mean method mean	8.75	7.59	6.32	5.18	4.22	2.92
Median CV	2.95	3.83	3.21	1.78	4.32	4.97
Overall Result Stats						
Median CV	1.80	1.90	1.48	1.90	1.78	2.09

