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EXTERNAL QUALITY ASSESSMENT



INTERNAL QUALITY CONTROL



REFERENCE MEASUREMENT SERVICES



EDUCATION & TRAINING

Weqas

GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

Identifying Errors using Problem Solving Tools - a Practical Case Workshop

Sam Jones / Nicola Blount

Case study Example



Scheme: Co-oximetry. Distribution Code: C300. Distribution Date: 17/08/20. Final. Report Issued: 9/09/20							
Total Haemoglobin (g/L)	Sample 1	Sample 2	Sample 3				
Reported Result	225.0	171.0	200.0				
Overall Mean	162.24	175.49	118.64				
Method Mean: Gem Premier 4000	155.39	168.76	115.36				
Instrument Mean: Gem Premier 4000	155.39	168.76	115.36				
Your results are compared against	155.39	168.76	115.36				

Good
Acceptable
Unacceptable iscuss with QC officer

Section SDI scores for this distribution

Section	
Overall	** 6.01
Total Haemoglobin	** 7.72
Oxyhaemoglobin	** 4.29
Carboxyhaemoglobin	** 3.47
Methaemoglobin	** 8.57





Cumulative Submitted results

	C294	C295	C296	C297	C298	C299	C300
Sample 1	169.0	?	119.0	?	?	?	225.0
Sample 2	140.0	?	170.0	?	?	?	171.0
Sample 3	115.0	?	142.0	?	?	?	200.0

	Key
?	Analyte enrolled but no results returned
N/A	Not enrolled for this analyte

A Performance Alert

At least 1 sample in the current distribution with a very poor score - |SDI| > 3

At least 2 samples in current/prior distribution with poor score - |SDI| > 2

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Overall Performance: Sample 2 acceptable / good performance. Samples 1 and 3 unacceptable.

SDI Scores on Manager's Summary page: All 4 analytes show SDI scores >3.

Analyte result table: (based on excerpt shown): Total Hb reported results much higher than the method mean and overall mean. Samples 1 and 3 highlighted red indicating poor SDI scores (>2).

Running Scores:. Lab had been sent a PP letter for non-returns and SDI >2. Graph shows good performance at C294 and C296, and non returns for all other distributions apart from C300.

Cumulative Bias Plot: Shows good performance for all samples reported over last 6 months apart from the 2 for this distribution. These samples are shown as being higher than 35.6 g/L above the target value.

Performance Alert: Several samples with high SDIs.

Error identified: Sporadic performance with some high SDIs and poor performance (positive bias), plus sporadic non returns.

Cause identified (feedback from the site): Pre-analytical sample handling for the poor performance. Incorrect choice of analytes for assay for one of the non returns, picked up prior to result submission and missing samples as the reason for the other non return.

C300	Sample 2 – results OK Samples 1 & 3 - ?incorrectly reconstituted.
C299	Incorrect analysis was performed – Blood gas analysis was performed instead of cooximetry.
C298	Samples could not be located on the ward



Lab: ## . Scheme: Blood Gas. Distribution Code: P302. Distribution Date: 19/10/20. Final. Report Issued: 6/11/20



Section SDI scores for this distribution

Section	#######
Overall	1.32
pН	N/S
[H+]	0.74
pCO2	0.41
pO2	** 3.79
Actual Bicarb	0.35

SDI Code	Meaning
N/A	Not enrolled for this analyte
?	Analyte enrolled but no results returned
N/S	This analyte not scored
NNR	Non-numerical results
**	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.

A user guide "How to interpret your report" is available to download as a PDF file from the resources area of our website at http://www.weqas.com/resourcelibrary

Case study 1

***** Please note*******

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

Weqas

Lab Code: ## · Section: ###### · Instrument: i-STAT

Scheme: Blood Gas. Distribution Code: P302. Distribution Date: 19/10/20. Final. Report Issued: 6/11/20					
pO2 (kPa)	Sample 1	Sample 2	Sample 3		
Reported Result	28.0	16.5	21.1		
Overall Mean	22.68	12.03	17.04		
Method Mean: i-STAT	21.97	13.95	17.77		
Instrument Mean: i-STAT	21.97	13.95	17.77		
Your results are compared against	21.97	13.95	17.77		

	Good
	Acceptable
Di	Unacceptable scuss with QC officer







Cumulative Submitted results

	P296	P297	P298	P299	P300	P301	P302
Sample 1	12.4	19.0	21.6	22.7	26.3	20.7	28.0
Sample 2	22.0	25.0	25.9	18.3	21.2	8.0	16.5
Sample 3	16.1	18.7	15.4	8.7	14.2	18.3	21.1
Sample 4	N/A	N/A	?	N/A	N/A	N/A	N/A

Key				
?	Analyte enrolled but no results returned			
N/A	Not enrolled for this analyte			

A Performance Alert

At least 1 sample in the current distribution with a very poor score - |SDI| > 3

At least 2 samples in current/prior distribution with poor score - |SDI| > 2

Your results show a significant consistent bias. Please discuss your results with your EQA Officer



Overall Performance: Poor. All samples highlighted red.

SDI Scores on Manager's Summary page: pO₂ SDI 3.79. All other analytes have good SDI scores.

Analyte result table: Reported result shows positive bias to i-STAT mean (this is the target mean).

Running Scores: Graph shows poor performance for the last 6 months with several results shown as arrows on the graph. This indicates that the SDI score is >3 for those samples. All poor scores are positive scores, meaning the results are positively biased to the target value.

Cumulative Bias Plot: Again this shows consistent positive poor performance across the last 6 months. Poor performance is not necessarily associated with a particular concentration range, as samples of the same value have good SDIs on some months.

Error identified: Significant consistent bias stated. As we have identified, this is a consistent positive bias.

Cause identified (feedback from the site):

The gas instrument is a mobile instrument that is returned to base for EQA to be completed. EQA had been stored in the fridge overnight and assayed first thing in the morning when instrument returned. Investigation showed that samples were likely not brought to room temperature. Pre-analytical handling practices were amended and the site now generally has acceptable / good performance.

Repeat samples were dispatched for investigation.

	Sample 1	Sample 2	Sample 3		
Original result	27.4	17.0	22.0		
Room temp' result	24.7	15.3	18.8		
i-STAT method mean	22.68	13.95	17.77		

Case study 2

Lab Code: ## · Section: ###### · Instrument: CoaguChek Pro II

Lab: ## . Scheme: POCT INR Distribution Date: 11/01/22. F	. Dis inal.	tribution Code: IN0122. Report Issued: 17/02/22		Scheme: POCT INR. Distribution Code: Distribution Date: 11/01/22. Final. Report Iss	IN0122. sued: 17/02/22
This Distribution	3	· · ·	All SDI Ranges	INR (units)	Sample 1
Overall Lab SDI: 0.38	2 -				1.50
97 5th centile: 1.42	1 -	•	> 2 Poor	Reported Result	4.50
1.42				Overall Mean	3.676
	0 -	IN0121 IN0321 IN0521 IN0721 IN0921 IN1121 IN0122 Distribution	•	Method Mean: CoaguChek Pro II	3.717
				Instrument Mean: CoaguChek Pro II	3.717
		Median 🛶 Sec SDI 📃 97.5th		Your results are compared against	3.717

Section SDI scores for this distribution

Section	######
Overall	** 2.66
INR	** 2.66





The following comments were submitted for this distribution:

Section name	Comment submitted				
######	strip lot number: 0321209309				
	operator: ######				

Cumulative Submitted results



Good

Acceptable

Unacceptable **Discuss with QC officer**

There are no current performance alerts for this analyte



Analyte: INR

Overall Performance: Unacceptable SDI Score on Manager's Summary page: 2.66 Analyte result table: Shows positive bias to Roche Coaguchek mean (4.5 vs 3.717). Running Scores: Graph shows only 2 distributions reported over last 7 distributions. One showed acceptable performance. This distribution shows poor performance (SDI >2). Cumulative Bias Plot: Sporadic returns. Bias shown of 0.2 at IN0321 and 0.7 at IN0122. Cumulative Submitted Results Table: Clearly shows non returns for all but 2 distributions within the 12 month period that the report covers.

Cause identified (feedback from the site):

IN0122 was submitted to Weqas however the strip lot number provided on the return is actually a Glucose strip lot number. We believe a Glucose test was carried out and consequently this result was out of consensus. For the non-returns, we have discovered that the INR machine had been moved from Ward X8 and it has been located on Ward Y8. Hopefully returns will improve now machine location is confirmed.



Case Study 2: Current Performance





Your overall performance for this analyte is: Good

. There are no current performance alerts for this analyte

There are no Wegas or Participant supplied comments for INR for this distribution.



Case study 3

Lab: Scheme: HbA1c. Distribution Code: HC0521. Distribution Date: 25/05/21. Final. Report Issued: 21/06/21



All S	All SDI Ranges									
<1	Good	1								
1 - 2	Acceptable] [
> 2	Poor									
		ľ								

Lab Code:

Section:

Scheme: HbA1c. Distribution Code: HC0521. Distribution Date: 25/05/21. Final. Report Issued: 21/06/21 HbA1c IFCC (mmol/mol) | Sample 1 | Sample 2 Good Reported Result 32.0 37.0 Acceptable Overall Mean 37.49 33.06 Unacceptable Method Mean: DCA 2000 / Vantage 38.39 33.90 Discuss with QC officer Instrument Mean: DCA Vantage 38.34 33.87 36.90 32.90 Reference Values Your results are compared against 36.90 32.90

Amb Unit · Instrument: DCA Vantage

Section SDI scores for this distribution

Section	Amb Unit
Overall	** 2.18
HbA1c IFCC	** 2.18





Cumulative Submitted results

	H295	H296	H297	H298	H299	HC0421	HC0521		Key
Sample 1	43.0	?	32.0	?	?	?	32.0	?	Analyte enrolled but no results returned
Sample 2	43.0	?	69.0	?	?	?	37.0	N/A	Not enrolled for this analyte
Sample 3	N/A	?	N/A	?	N/A	?	N/A		

A Performance Alert

At least 2 samples in current/prior distribution with poor score - |SDI| > 2



Analyte: HbA₁c

Overall Performance: Both samples showing poor performance.

SDI Score on Manager's Summary page: 2.18

Analyte result table: Sample 1 shows negative bias to DCA Vantage mean, Sample 2 shows positive bias to DCA Vantage mean.

Running Scores: Graph shows only 2 samples within 'good' range. The rest show acceptable or poor SDI scores. **Cumulative Bias Plot:** Sporadic performance. Most samples acceptable or poor, with some good performance. Both positive and negative bias noted, spanning -5 to +8 mmol/mol.

Cumulative Submitted Results Table: Shows good performance at H297. Several months of non returns. Poor performance at H295 and HC0521.

Error identified: Mixed error. Potentially a clerical error, inexperienced users, faulty equipment.

Suggest that samples were transposed in this case, either for assay or at data entry stage.

Reported Results for all sections with Method Means and SDs

Weqas

Distribution: HC0521 Distribution Date: 25 May, 2021 Analyte: HbA1c IFCC (mmol/mol) Method: DCA 2000 / Vantage

	Distribution Code : HC0521	Sent or	n: 25/05/21	
HbA1c IFCC (mm	ol/mol)	1	2	
AAO		40.0	36.0	
ABN		40.0	35.0	
ABN		37.0	32.0	
ABN		38.0	33.0	
ABN		41.0	35.0	
ABN		38.0	33.0	
ABS		36.0	36.0	
ACD		36.0	32.0	
AEB		41.0	35.0	
AFI				
AFL		32.0	37.0	
AFL				
AFL				
AGV		38.0	35.0	
AGV				
AGV		40.0	32.0	
AGV		39.0	35.0	
AGV		38.0	34.0	
AGV		41.0	33.0	
AGV				
AGW		38.0	35.0	
AGW		37.0	34.0	
AGW		40.0	34.0	
AGW		39.0	33.0	
AGW				
AGW		39.0	35.0	
AGW		36.0	31.0	
AHN		39.0	33.0	
		00.0	00.0	

Case study 4

Lab: ## . Scheme: Blood Gas. Distribution Code: BG0322. Distribution Date: 21/03/22. Final. Report Issued: 20/04/22



Section SDI scores for this distribution

Section	#######
Overall	1.00
рН	N/S
[H+]	1.52
pCO2	1.55
pO2	** 3.72
Actual Bicarb	0.13
Sodium	0.14
Potassium	0.20
Ionized Calcium	1.24
Glucose	0.35
Lactate	0.10

Lab Code: ## · Section: ###### · Instrument: ABL 90 flex

Scheme: Blood Gas. Distribution Code: BG0322. Distribution Date: 21/03/22. Final. Report Issued: 20/04/22									
pO2 (kPa)	Sample 1	Sample 2	Sample 3	Sample 4					
Reported Result	24.0	20.1	16.4						
Overall Mean	22.02	17.13	11.87						
Method Mean: ABL 90 FLEX	22.29	16.77	10.63						
Instrument Mean: ABL 90 flex	22.29	16.77	10.63						
Your results are compared against	22.29	16.77	10.63						

Good
Acceptable
Unacceptable Discuss with QC officer





Cumulative Submitted results

	BG0821	BG0921	BG1021	BG1121	BG0122	BG0222	BG0322		
Sample 1	10.6	14.6	17.5	12.0	23.7	18.6	24.0		Key
Cample 2	46.3	20.2	20.0	40.2	46.2	44.5	20.4	?	Analyte enrolled but no results returned
oampie z	10.3	20.2	20.9	19.2	10.2	11.4	20.1	NUA	Not accolled for this analyte
Sample 3	21.9	3.66	23.5	N/A	6.72	20.3	16.4	INVA.	Not enrolled for this analyte
Sample 4	N/A	?	N/A	N/A	N/A	N/A	?		

A Performance Alert

At least 1 sample in the current distribution with a very poor score - |SDI| > 3

At least 2 samples in current/prior distribution with poor score - |SDI| > 2

Your results show a significant consistent bias. Please discuss your results with your EQA Officer

Your results show a consistent bias over an extended period. Please discuss your results with your EQA Officer.



Analyte: pO₂

Overall Performance: Sample 1 acceptable, Samples 2 and 3 unacceptable.

SDI Scores on Manager's Summary page: 3.72

Analyte result table: Reported result shows positive bias to ABL90 Flex mean (this is the target mean).

Running Scores: Graph shows poor performance for the last 6 months. All poor scores are positive scores, meaning the results are positively biased to the target value. Many are within acceptable range but several samples show very poor performance.

Cumulative Bias Plot: Again this shows consistent positive poor performance across the last 6 months. Bias can be seen across the concentration range.

Cumulative Submitted Results Table: Show consistent poor performance since BG0921. This does not necessarily seem to be concentration dependent.

Error identified: Significant consistent bias stated on the performance alert, 'consistent bias over an extended period'. As we have identified, this is a consistent positive bias.

Cause identified (feedback from the site): Pre-analytical sample handling.

Lab Feedback



- Practice on Sampling processes has been revisited and noticed staff has different practices in terms of processing and methods of EQA sampling. Training has been revalidated for all the Critical Care Technologist team regarding Weqas sampling process and methodology. Including the reiteration of the Weqas sampling instructions.
- Radiometer has been contacted and suggested action has been provided and follow.
- 1. Check if there were any sample error messages reported on the EQA samples involved?
- 2. Check the analyser's calibration performance for the parameters involved both before and after the time the EQA sample was performed. Look at calibration trend for parameter involved, (calibration log, filter, 30 days, apply, view trend, select parameter). If calibration performance is not consistent consider changing the membrane or Sensor Cassette as appropriate for the type of analyser.
- 3. If calibrations are stable then the Internal (Radiometer Auto check) Quality Control trend plot (Levy-Jennings) should be checked for any inconsistencies. If plot shows inconsistencies has this existed both before and after a membrane or Sensor Cassette change? Consider changing the membrane or Sensor Cassette.
- 4. If the analyser's calibrations and quality controls are performing well, but you are still concerned about any parameter's measuring performance, then we recommend that some whole blood sample comparisons should be done. This must be done using the same sample (i.e. same syringe, ensuring proper mixing before each sampling) on 2 or more analysers and we recommend varying which order the samples are tested on the analysers to rule out variations due to the sample aging. Ideally comparison should be done between the same models of analyser, to avoid differences in measuring methods etc.
- 5. It also might be useful to check with the EQA provider if they have any reports of problems with their samples.
- Sample Distribution schedule has been put on Rota planning and as soon the samples arrived as much as possible to perform the process.