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Results of a Pre-analytical EQA Programme for Serum Indices

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Introduction

Whilst most Pre-analytical EQA schemes focus on the data counting of the number of rejected samples, Weqas has developed a programme to evaluate the laboratory's ability to detect unsuitable samples and assess their testing protocols for the analytes affected.

Method

In 2011 users of the Weqas Serum Chemistry programme were enrolled onto the indices programme with additional users free to enrol into the serum indices only component. Over 200 users now report results with the majority using semi-quantitative methods. Samples were spiked with conjugated and unconjugated bilirubin to provide total bilirubin covering a range of 60-460 μ mol/L, Intralipid to a triglyceride range of 3 to 12.6 mmol/L and whole blood to provide a haemoglobin range of 0.4 to 3g/L. Two matched pools were distributed, one containing the interferant and the other the base serum.

Table 1 – Units of reporting

Analyser Type	Serum Index	Result Units	Action to Take	Conversion factor	
Roche Cobas and Modular	Haemolysis	mg/dL	to g/L	[÷ 100]	
		μmol/L	to g/L	[x 0.0161]	
	Icterus	mg/dL	to μmol/L	[x 17.1]	
	Lipaemia	mg/dL	to mmol/L	[x 0.0114]	
	Haemolysis	mg/dL	to g/L	[÷ 100]	
Siemens Advia Analysers	lcterus	mg/dL	to μmol/L	[x 17.1]	
	Lipaemia	mg/dL	to mmol/L	[x 0.0114]	
		g/L	to mmol/L	[x 1.14]	
	Haemolysis	g/L	None		
Abbott Architect Analysers	lcterus	μmol/L	None		
	Lipaemia	mmol/L	None		
Beckman Coulter AU and Dx Analysers, Ortho Clin. Diagnostics Vitros, Siemens Dimension	Haemolysis	Ordinal / mg/dL	to g/L [‡]	[÷ 100]	
	Icterus	Ordinal / mg/dL	to μmol/L [‡]	[x 17.1]	
	Lipaemia	Ordinal / mg/dL	to mmol/L [‡]	[x 0.0114]	

Table 3 – Qualitative results

[‡]Only if semi-qualitative results are reported.

	IQN H 0.3g/L		IQQ		IQT		IQW		IQZ		
					L	L			L		
Quant Mean			52 umol/L		6.3 mmol/L		347 u	mol/l	3.6 mmol/L		
Analyser	Results	No.	Results	No.	Results	No.	Results	No.	Results	No.	
Interpretation	+		+		+++		+++		++		
Advia	Neg/- (0-0.22)	12	Neg, -	1	Neg,-		Neg,-	2	Neg,-		
	+ (0.23-1.0)	1	+	26	+		+		+		
	++ (1.1-2.33)		++		++		++	6	++	29	
	+++ (2.34-3.78)		+++		+++	27	+++	22	+++		
	++++ (3.79 ->)		++++		++++		++++		++++	1	
% correct		8%		96%		100%		73%		97%	
Interpretation	+/0.5-0.99		+		++++		+++		+++		
Beckman AU	Neg/-/<0.5		Neg, -	29	Neg,-	2	Neg,-		Neg,-		
	+/0.5-0.99	24	+	12	+		+		+		
	++/1.00-1.99		++		++		++		++	1	
	+++/2.00-2.99		+++		+++		+++	47	+++	25	
	++++/3.00-5.00		++++		++++	23	++++	1	++++	9	
	++++/>5.00		++++		+++++	17	+++++		+++++		
% correct		100%		29%		55%		98%		71%	
Interpretation	1 – 2/0.0-0.75		2-4		9-10		11-17		6 - 8		
Beckman DX	Neg/0		Neg, 0-1		Neg, 0-1		Neg, 0-1		Neg, 0-1		
	1-2 (0.0-0.75)	3	2-4	5	2		2-4		2		
	3 – 4 (0.75-1.50)		5-10		3-5		5-10		3 - 5	1	
	5 – 6 (1.50-2.25)		11-17		6-8		11-17	5	6 - 8	4	
	7 – 8 (2.25-2.75)		18-20		9-10	5	18-20		9- 10		
	9 – 10 (2.75-3.50)										
% correct		100%		100%		100%		100%		80%	
Interpretation			+		+++		+++		+++		
Piccolo	Neg/-		Neg/-	5	Neg,-		Neg,-		Neg,-		
	+		+		+		+		+		
	++		++		++		++		++		
	+++		+++		+++	4	+++	3	+++	6	
			++++		++++		++++		++++		
% correct				0%		100%		100%		100%	

Table 2 – Semi quantitative results

Dis	tribution:	IQN Base	IQN Base +H	IQQ Base	IQQ Base +I	IQT Base	IQT Base +L	IQW Base	IQW Base+I	IQZ Base	IQZ Base+L
Haemolys	sis Index (g/L)	Dasc		Base	• •	Base	• •	Dasc	Base	Dasc	<u> </u>
riaemoi,	Overall Mean		0.26	0.01	0.01	0.01	0.03	0.01	0.01	0.02	0.03
	Overall SD	0	0.04	0.01	0.01	0.01	0.05	0.01	0.01	0.01	0.03
	Number	137	139	177	178	183	181	180	182	174	164
	Target	0	0.4	0	0	0	0	0	0	0	0
Architect	Mean	0	0.23	0	0.02	0	0	0	0.02	0.02	0.01
	SD	0	0.02	0	0.01	0.01	0.01	0	0.01	0.01	0.01
	Number	35	37	43	45	40	36	43	45	45	43
Cobas	Mean	0.03	0.27	0.01	0.01	0.01	0.03	0.01	0	0.02	0.04
	SD	0.02	0.03	0.01	0.01	0.01	0.06	0.01	0	0.01	0.04
	Number	98	98	125	125	136	136	132	130	121	116
\ dvia	Maan	_	0.4	0.03	0.01	0.01	0.05	0.01	0.05		
Advia	Mean SD	0 0	0.4 0	0.02 0	0.01	0.01 0	0.05	0.01	0.05		
	่ Number	2	2	3	3	3	3	3	3		
	- Hannber)	J	J					
Icterus In	dex (umol/L)			_							
	Overall Mean	4.54	3.79	3.32	52.17	3.11	0.12	3.2	347.71	1.96	0.1
	Overall SD	4.59	3.78	3.35	9.97	3.2	0.75	2.83	71.01	2.01	0.52
	Overall Number	139	139	177	175	187	176	182	182	176	168
	Target	0	0	0	60	0	0	0	360	0	0
				_						J	
Architect	Mean	8.58	5.94	6.92	40.44	6.34	0.78	5.76	233.05	3.89	0.54
	SD	1.34	1.5	1.16	3.7	1.24	3.16	0.95	12.84	0.87	1.38
	Number	37	37	45	42	43	34	44	44	46	42
Cobas	Mean	2.83	2.78	2.06	56.54	2.02	0	2.31	388.93	1.36	0
	SD	3.86	3.68	2.95	7.45	2.84	0	2.73	23.18	1.88	0
	Number	99	99	123	124	137	136	131	123	122	118
Advia	Mean	8.6	8.6	5.75	56.49	7.56	3.42	4.28	416.8		
	SD	0	0	0.88	10.99	1.02	2.42	1.22	57.57		
	Number	2	2	3	3	3	3	3	3		
Linagonia	Inday (manal 4)										
Lipaemic	Index (mmol/L) Overall Mean	0.24	0.28	0.32	0.28	0.33	6.29	0.32	0.33	0.11	3.61
	Overall SD	0.24	0.28	0.32	0.28	0.33	0.91	0.32	0.33	0.11	0.49
	Number	139	139	174	175	179	181	184	184	175	169
	Target	0	0	0	0	0	9.0	0	0	0.00	5.0
		0.15	0.46	0.45	0.44	0.4-	4.00	0.4=	0.00	0.00	2.00
Architect	Mean SD	0.12 0.03	0.16 0.03	0.16 0.02	0.11	0.17 0.02	4.96 0.24	0.17	0.02	0.02 0.01	2.99 0.14
	טכ Number	37	37	41	42	39	42	44	45	45	46
Cobas	Mean	0.28	0.31	0.37	0.33	0.38	6.77	0.37	0.43	0.15	3.88
	SD	0.06	0.05	0.05	0.04	0.06	0.52	0.04	0.04	0.02	0.26
	Number	98	98	119	120	131	128	126	124	115	113
Advia	Mean	0.2	0.3	0.35	0.29	0.29	6.14	0.34	0.39		
	SD	0	0	0	0.01	0.05	0.13	0.01	0.06		
	Number	2	2	3	3	3	3	3	3		

Results

Key to

samples

H

effect

Wide variety of units were reported for the serum indices apart from the Abbott Architect where all users reported in SI units (Table 1). Semi-quantitative results for the last 2 years are provided in Table 2. For the haemolysed sample IQN, with Hb added to a concentration of 0.4 g/L the overall mean was 0.26 g/L (SD 0.04). For qualitative results, Table 3, only 1 out of 13 laboratories using the Siemens Advia reported a positive '+' (0.23-1.0 g/L) result with all the Beckman AU and Dx users identifying the correct H index. The icteric sample, IQQ spiked to 60 µmol/L gave an overall mean of 52.2 μmol/L (SD 9.97). For the qualitative methods, all the Beckman Dx users reported a positive I index, 96% Siemens Advia users identified the icteric sample as '+', however, 71% of Beckman AU and all 5 users of the Abaxis Piccolo reported a negative I index. All users correctly identified the icteric sample at a bilirubin concentration of 360 µmol/L for distribution IQW. For the lipaemic samples, IQT and IQZ, the overall mean estimated triglyceride was 6.29 mmol/L, (SD 0.91) and 3.61 (SD 0.49) respectively. All users correctly identified the lipaemic samples on qualitative analysis for IQZ, however 2 out of 42 Beckman AU reported a negative L index for sample IQT with the majority of results reporting + and 5+ L index.

It was observed that for certain platforms the interferant often had an effect on other indices (highlighted in blue in Table 2). For haemolysed samples, a small decrease in I index result was observed for the Architect compared with the base sample. For icteric samples there was no observed difference between the base and interferant for the H and L indices at a concentration of 60 μ mol/L , however wider variation of results were observed for the H indices for the Advia compared with the base at 360 μ mol/L. For lipaemic samples a wider variation of results was observed for the H index for the Cobas and Advia. A small decrease in the I index was observed for all the analysers. This would require further investigation.

Conclusion

There appears to be little harmonisation of reporting for serum indices even within users of the same instrument. It is important that laboratories are aware of potential interferences in their assays, are aware of which analytes could be affected, have the ability to detect the potential interferences and have systems in place to ensure the accuracy of results when these interferences are present. Users should also be aware of the potential effect of the interferant on more than one index.