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UKAS PROFICIENCY TESTING 4301

A Review of Lactate Performance on the Weqas Blood Gas External Quality Assessment (EQA) Programme – A comparison of POCT and Lab Instruments and their suitability for use in Sepsis Management.

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Introduction

According to the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3), sepsis is a syndrome defined as life-threatening organ dysfunction due to a dysregulated host response to infection [Shankar-Hari, 2016; Singer, 2016].

Septic shock is a subset of sepsis, which describes circulatory, cellular, and metabolic abnormalities that are associated with a greater risk of mortality than sepsis alone. People with septic shock can be identified using the clinical criteria of persisting hypotension requiring vasopressor therapy to maintain a mean arterial pressure of 65 mmHg or more, and serum lactate level greater than 2 mmol/L despite adequate volume resuscitation [Singer, 2016; NICE, 2024].

National Institute for Health and Care Excellence (NICE) Guideline [NG51]: 'Sepsis: recognition, diagnosis and early management' recommends lactate measurement as part of risk stratification and management of suspected sepsis in acute hospital settings.

Lactate was introduced as part of the Weqas Blood Gas EQA programme in 2001, with 33 laboratory enzymatic methods and 295 blood gas analysers in use at the end of the first 5 years compared with 43 enzymatic and 2116 blood gas or lactate meters used in 2023.

Current performance for both laboratory and POCT methods were assessed at clinical decision thresholds. The Weqas Blood Gas Programme assesses both laboratory and method performance, including bias, within and between batch imprecision.

Method

Three samples were distributed monthly with a lactate range of 0.4 to 6.4 mmol/L provided over the year. The programme assessed both laboratory and method performance, including linearity, bias, within batch and between batch imprecision.

The performance of participants in 2023 using 11 different POCT instruments, 1 handheld lactate specific instrument, and 6 different laboratory instruments were assessed.

Table 1. Change in Blood gas analyser type and growth of POCT analysers from 2001 to 2023 on the Weqas Blood Gas EQA Programme

Analyser Type	Year					
	2023	2020	2016	2010	2006	2001
Conventional electrodes	127	244	541	947	853	505
Multi use Cartridge	1876	1440	1033	541	239	14
Optical sensor	13	16	28	39	34	13
Single use Cartridge	427	338	269	137	84	11
% POCT Analysers	**94.8**	**88**	**71.1**	**43.1**	**29.5**	**7**
Total	2443	2038	1871	1664	1210	543

Results and Discussion

Figure 1 shows the overall Precision Profile (SD) for Lactate for BG0423 to BG0324. The current performance criteria are also shown. The current performance (SD) over the previous 12 months is well within the performance criteria. The current performance criteria are based on Milan Model 3 – state of the art, as there are no outcome study data or biological goals available. Figure 2 shows the precision profile as a CV. At concentrations above 2 mmol/L the CV was below 5%. At overall mean approximately 1.5 mmol/L the overall CV was 5-6%.

Figure 1 – Precision Profile (SD) for Lactate for BG0423 to BG0324.

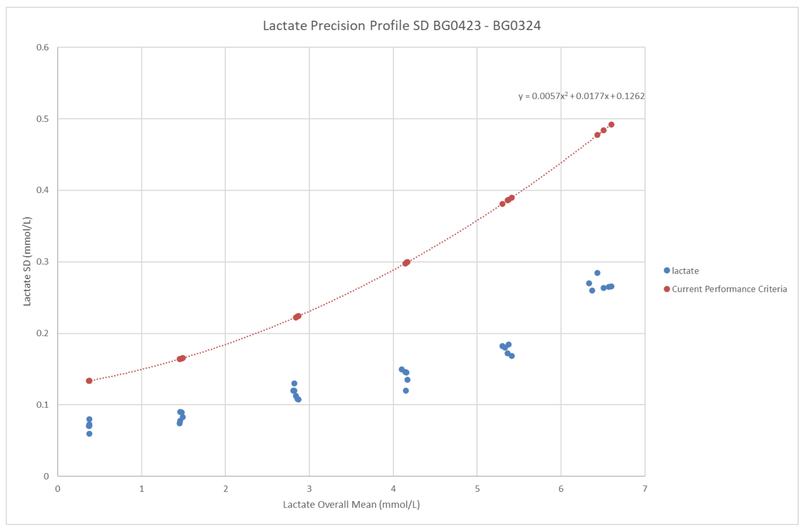
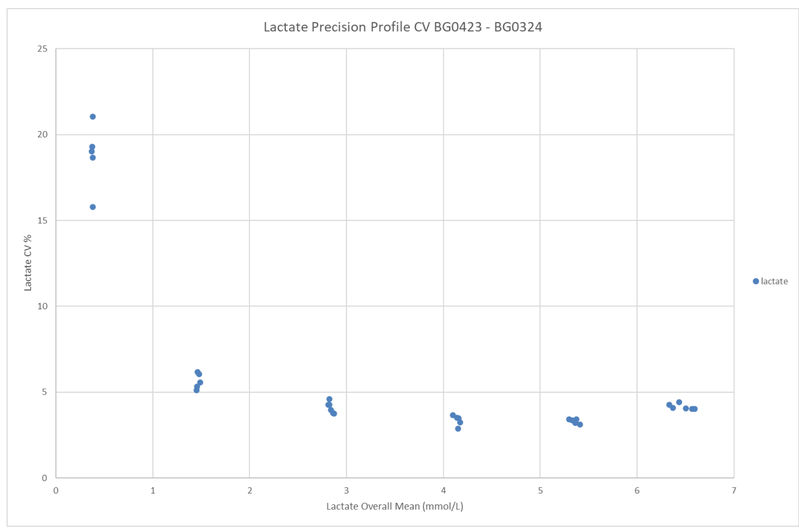


Figure 2 – Precision Profile (CV) for Lactate for BG0423 to BG0324.

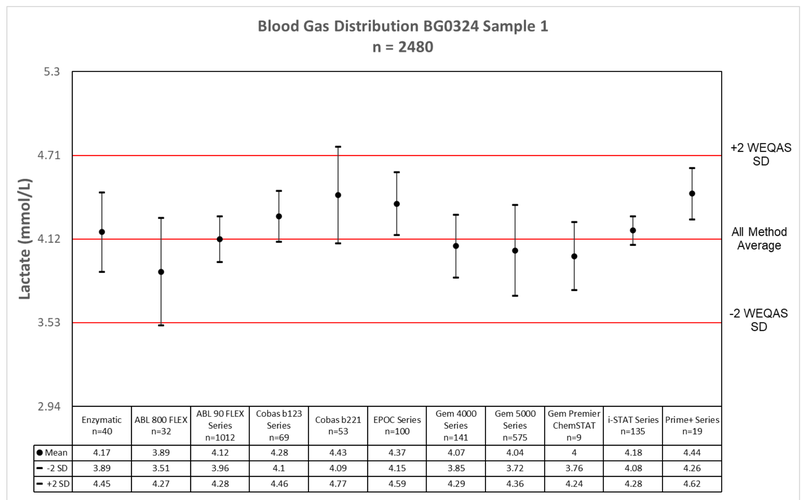


Figures 3, 4 and 5 show the bias of each instrument to the All-Method Average for distribution BG0324 (The All-Method Average was used in preference to the overall mean to allow equal weighting for each method group). Shown on the left-hand side is the enzymatic method group (laboratory instruments), followed by all POCT instruments.

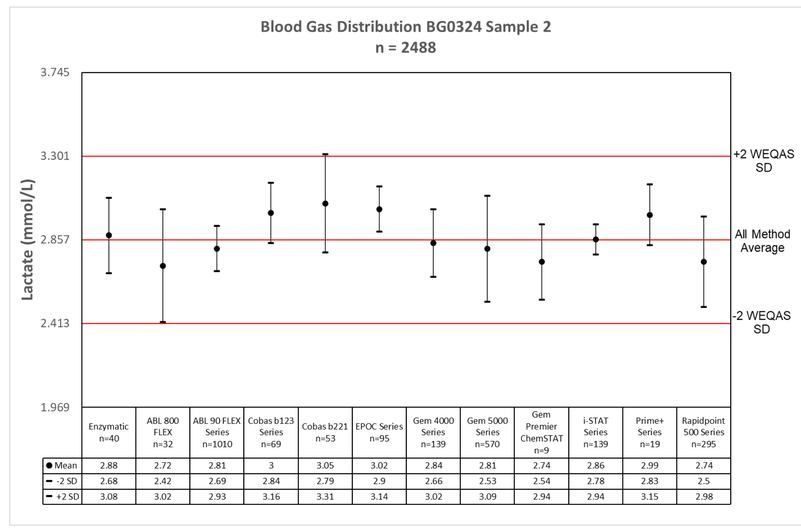
Figure 3 shows the bias at an All-Method Average of 4.12 mmol/L. The enzymatic method mean is 4.17 mmol/L showing a bias of 0.05 mmol/L to the All-Method Average. All POCT instruments show a bias of < 0.3 mmol/L at this clinical decision threshold, well within the allowable performance criteria. The I-bars show +/- 2 method SDs for each instrument.

The enzymatic method CV was 3.4%, allowable performance criteria is approximately +/- 13%. Most POCT instruments also had similar CVs to the enzymatic group, with CVs ranging from 1.9 to 4.9%.

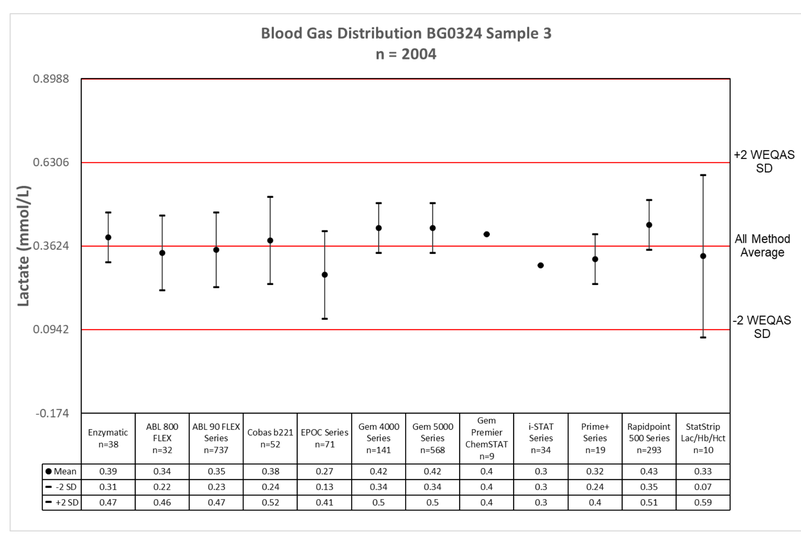
Figures 3, 4 and 5 show the bias of each instrument to the All-Method Average for distribution BG0324



	Enzymatic n=40	ABL 800 FLEX n=32	ABL 90 FLEX Series n=1012	Cobas b123 Series n=69	Cobas b221 n=53	EPOC Series n=100	Gem 4000 Series n=141	Gem 5000 Series n=575	Gem Premier ChemSTAT n=9	i-STAT Series n=135	Prime+ Series n=19
Mean	4.17	3.89	4.12	4.28	4.43	4.37	4.07	4.04	4	4.18	4.44
-2 SD	3.89	3.51	3.96	4.1	4.09	4.15	3.85	3.72	3.76	4.08	4.26
+2 SD	4.45	4.27	4.28	4.46	4.77	4.59	4.29	4.36	4.24	4.28	4.62



	Enzymatic n=40	ABL 800 FLEX n=32	ABL 90 FLEX Series n=1010	Cobas b123 Series n=69	Cobas b221 n=53	EPOC Series n=95	Gem 4000 Series n=139	Gem 5000 Series n=570	Gem Premier ChemSTAT n=9	i-STAT Series n=139	Prime+ Series n=19	Rapidpoint 500 Series n=295
Mean	2.88	2.72	2.81	3	3.05	3.02	2.84	2.81	2.74	2.86	2.99	2.74
-2 SD	2.68	2.42	2.69	2.84	2.79	2.9	2.66	2.53	2.54	2.78	2.83	2.5
+2 SD	3.08	3.02	2.93	3.16	3.31	3.14	3.02	3.09	2.94	2.94	3.15	2.98



	Enzymatic n=38	ABL 800 FLEX n=32	ABL 90 FLEX Series n=737	Cobas b221 n=52	EPOC Series n=71	Gem 4000 Series n=141	Gem 5000 Series n=568	Gem Premier ChemSTAT n=9	i-STAT Series n=34	Prime+ Series n=19	Rapidpoint 500 Series n=293	StatStrip Lac/Hb/Hct n=10
Mean	0.39	0.34	0.35	0.38	0.27	0.42	0.42	0.4	0.3	0.32	0.43	0.33
-2 SD	0.31	0.22	0.23	0.24	0.13	0.34	0.34	0.4	0.3	0.24	0.35	0.07
+2 SD	0.47	0.46	0.47	0.52	0.41	0.5	0.5	0.4	0.3	0.4	0.51	0.59

Figure 4 shows the bias at an All-Method Average of 2.86 mmol/L. The enzymatic method mean is 2.88 mmol/L showing almost no bias to the All-Method Average. All POCT instruments show a bias of < 0.2 mmol/L at this clinical decision threshold, well within the allowable performance criteria. The enzymatic CV was 3.5%, most POCT instruments had similar CVs (range 1.4 – 5.5%). Figure 5 shows the bias at an All-Method Average of 0.36 mmol/L. This sample is very low and well within the normal range, all POCT instruments show similar low bias and CV to the enzymatic group.

Conclusion

The mean bias of the POCT and laboratory instruments were not significantly different across a range of samples. The CV for most of the POCT instruments compared well with the enzymatic methods. An identical analytical performance specification was used within the programme for both POCT and laboratory instruments. Most instruments performed well at the clinical decision thresholds of 2 mmol/L and 4 mmol/L suggesting that lactate measurement on POCT blood gas analysers are suitable and appropriate for use in sepsis management.

Shankar-Hari, M., Phillips, G.S., Levy, M.L. *et al.* (2016) Developing a New Definition and Assessing New Clinical Criteria for Septic Shock: For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA* **315**(8), 775-787.
NICE (2024) *Suspected sepsis: recognition, diagnosis and early management*. National Institute for Health and Care excellence. https://www.nice.org.uk