Global Provider of Quality in Diagnostic Medicine

Blood Gas and Co-oximetry Scheme Guide

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Contents

1. Scheme details and repertoire

1.1 Blood Gas

Details:
The material is sourced from a competent subcontractor and conforms to the quality specification provided by Weqas. It is supplied in 2.5 ml sealed glass ampoules. Tonometered protein based aqueous material is used. A batch lasts approximately 12 months and consists of six levels covering the pathological range. Three of the six samples are randomly distributed each month

Number of samples sent with each distribution: 3
Frequency of distributions: every month
Material: protein based aqueous

Analytes :	**Range :**
pH	7 0 - 7.8
H^+	20 - 100 nmol/L
pCO_2	2-12 kPa
pO_2	4 - 40 kPa
Na^+	112 - 164 mmol/L
K^+	1.7 - 7.9 mmol/L
Ca^{++}	0.5 - 1.9 mmol/L
Cl	72 - 121 mmol/L
Magnesium	0.4 – 1.8 mmol/L
Glucose	2.6 - 19.2 mmol/L
Lactate	0.4 – 6.0 mmol/L
Urea	1.0 – 35 mmol/L
Creatinine	5.0 – 700 µmol/L
Haematocrit	0 – 70 %PCV

1.2. Co-oximetry

Details:
The material is sourced from a competent subcontractor and conforms to the quality specification provided by Weqas. It is supplied as 2 ml lyophilised vials with an integrated 2ml water reservoir. The material is prepared from lyophilised stroma-free bovine haemoglobin solutions with no dyes or additives. A batch lasts approximately 3 months and consists of 6 levels covering the pathological range. Three of the six samples are randomly distributed each month

Number of samples sent with each distribution: 3
Frequency of distributions: every month
Material: Bovine haemolysate

Analytes :	**Range :**
Total Haemoglobin	80 - 200 g/L
Carboxyhaemoglobin	1.7 - 17 %
Methaemoglobin	4 - 37 %
Oxyhaemoglobin	40 - 90 %

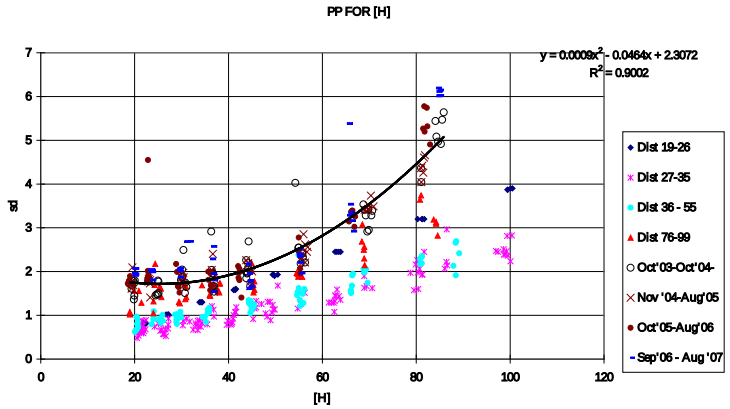
2. Statistical analysis

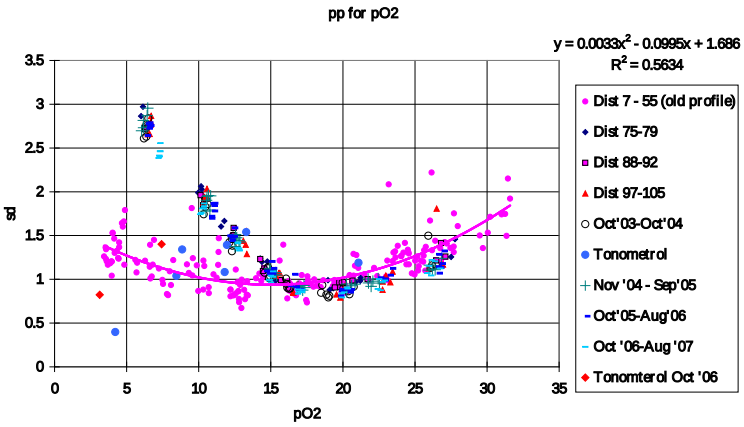
2.1 Reference values

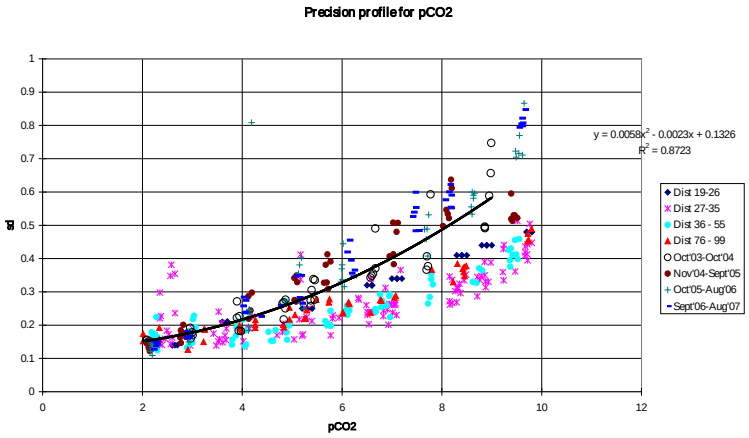
For Blood gases the trimmed method mean (instrument) is used as the target value. Participant's results are compared with their instrument mean. For co-oximetry the Total Hb is measured with the CNMetHb reference method. The instrument mean is used as the target value for the derivatives. Data using continuous spectra absorbance is also available for these analytes.

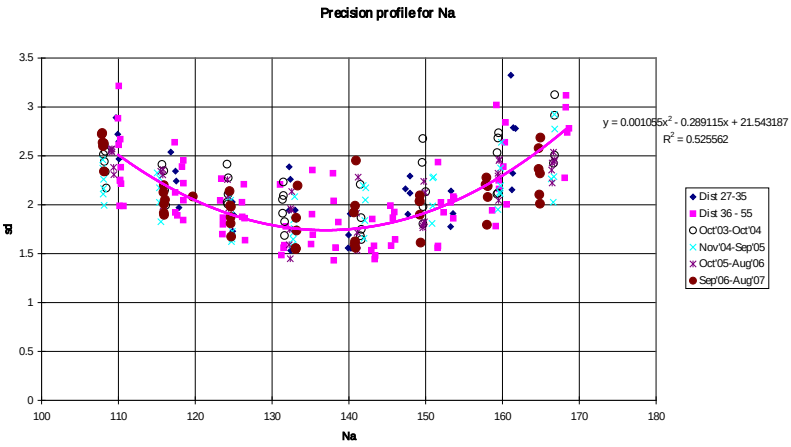
2.2 Performance Criteria

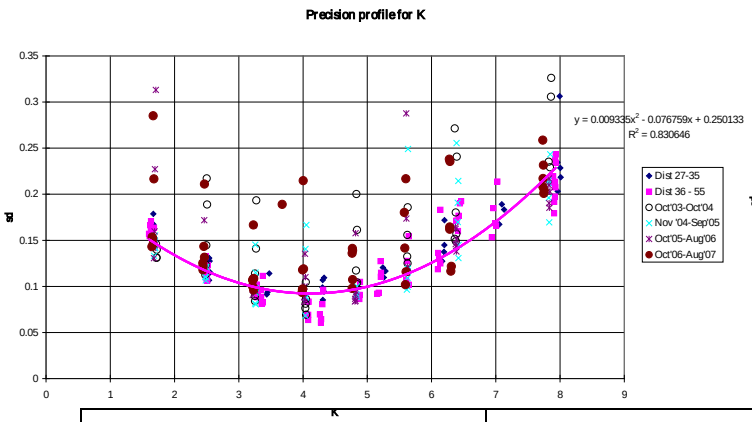
Standard deviation limits used in the report are based on precision profiles calculated over several batches and are fixed for a given level of analyte. They are reviewed yearly and reflect the state of the art of the methods used.

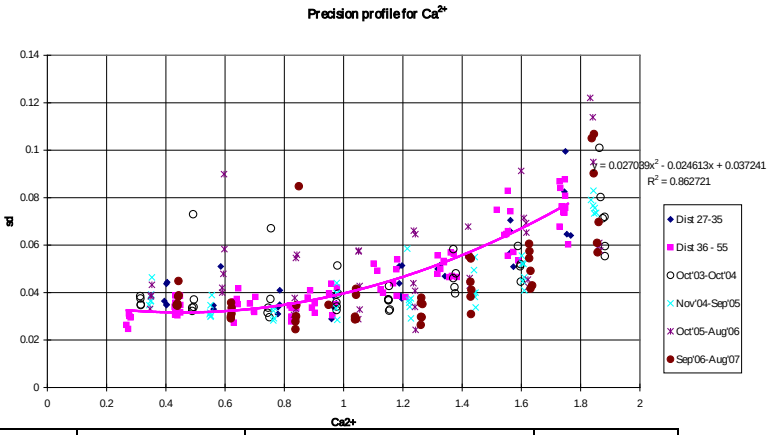


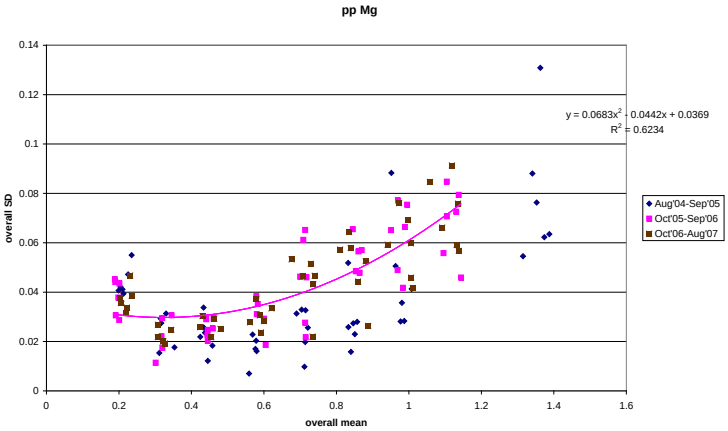


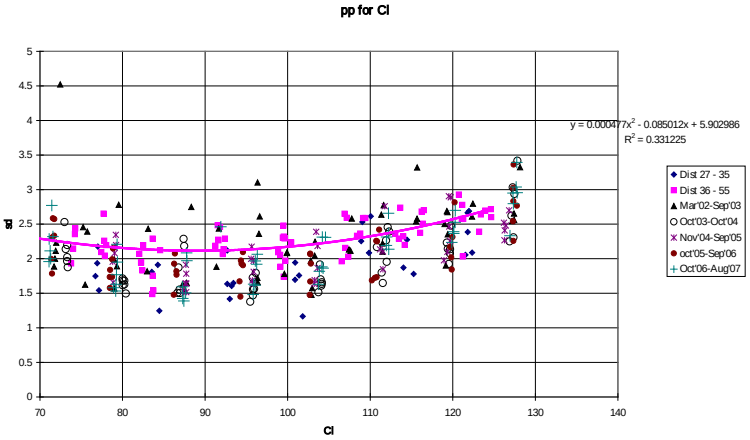


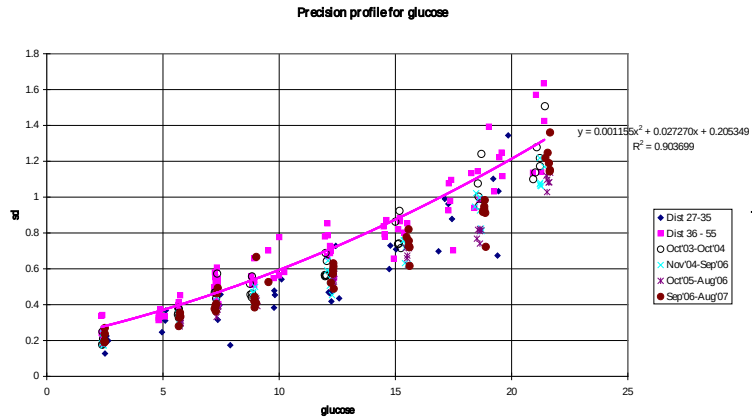


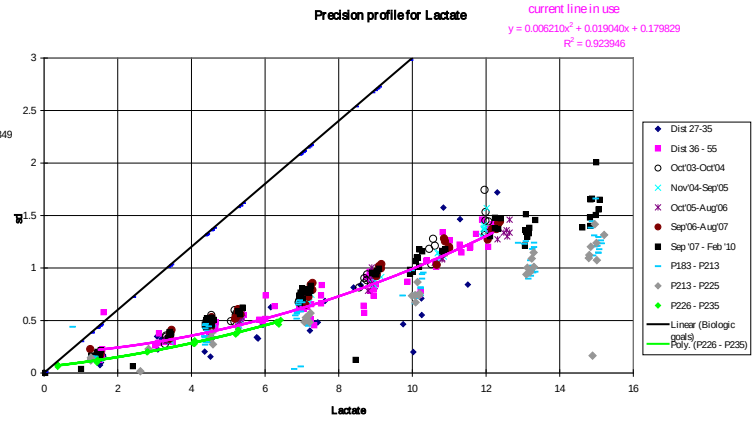


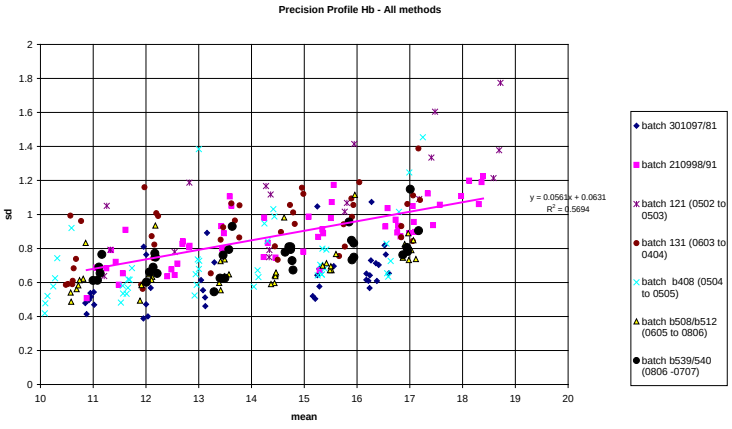


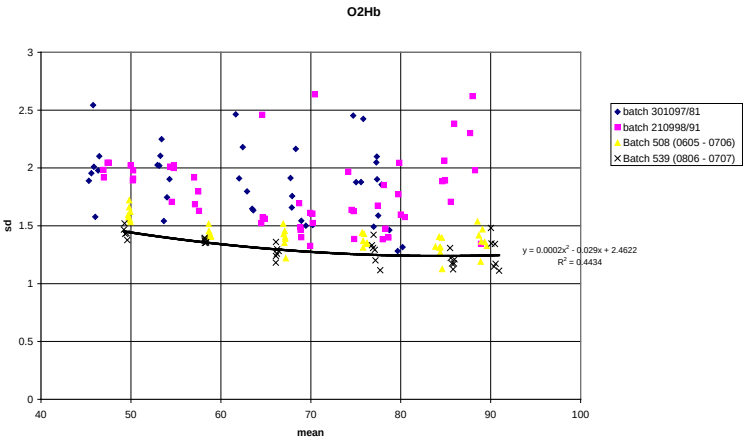

pp Mg
y = 0.0683x2 - 0.0442x + 0.0369
R2 = 0.6234
overall SD
overall mean
Aug'04-Sep'05
Oct'05-Sep'06
Oct'06-Aug'07

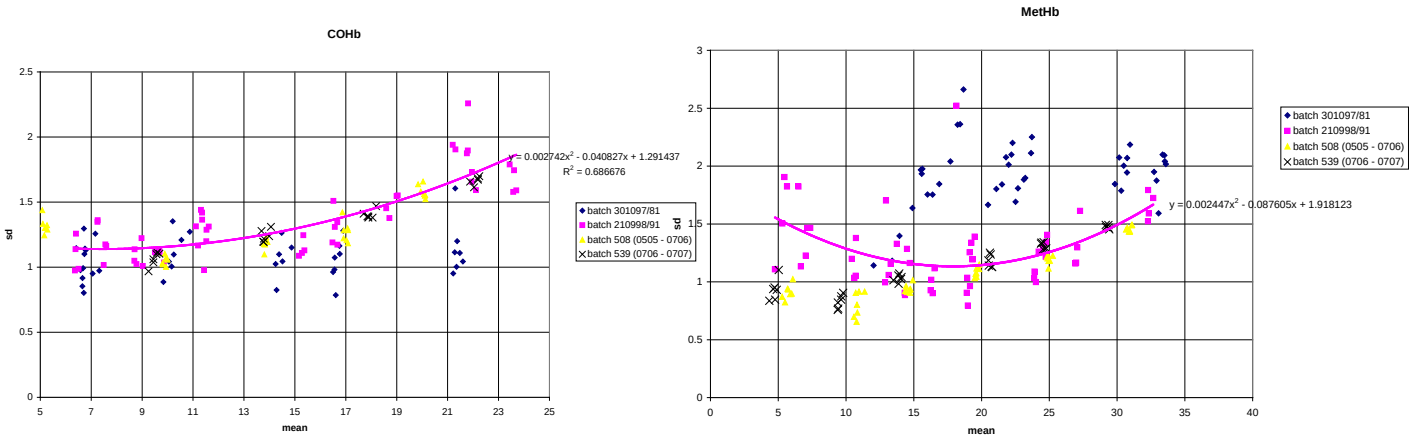

pp for Cl
y = 0.000477x2 - 0.085012x + 5.902986
R2 = 0.331225
sd
Cl
Dist 27 - 35
Dist 36 - 55
Mar'02-Sep'03
Oct'03-Oct'04
Nov'04-Sep'05
oct'05-Sep'06
Oct'06-Aug'07


Precision profile for glucose
y = 0.001155x2 + 0.027270x + 0.205349
R2 = 0.903699
sd
glucose
Dist 27-35
Dist 36 - 55
Oct'03-Oct'04
Nov'04-Sep'06
Oct'05-Aug'06
Sep'06-Aug'07


Precision profile for Lactate
current line in use
y = 0.006210x2 + 0.019040x + 0.179829
R2 = 0.923946
sd
Lactate
Dist 27-35
Dist 36 - 55
Oct'03-Oct'04
Nov'04-Sep'05
Oct'05-Aug'06
Sep'06-Aug'07
Sep '07 - Feb '10
P183 - P213
P213 - P225
P226 - P235
Linear (Biologic goals)
Poly. (P226 - P235)


Precision Profile Hb - All methods
y = 0.0561x + 0.0631
R2 = 0.5694
sd
mean
batch 301097/81
batch 210998/91
batch 121 (0502 to 0503)
batch 131 (0603 to 0404)
batch b408 (0504 to 0505)
batch b508/b512 (0605 to 0806)
batch b539/540 (0806 -0707)


O2Hb
y = 0.0002x2 - 0.029x + 2.4622
R2 = 0.4434
sd
mean
batch 301097/81
batch 210998/91
Batch 508 (0605 - 0706)
Batch 539 (0806 - 0707)



2.3 Data analysis and interpretation

Please refer to the accompanying Participants Manual for full details on statistical analysis and interpretation of results.

pH assessment.
As pH is a logarithmic function of H^+ ion concentration, WEQAS assess pH performance by converting results to H^+ ion concentration. SDI scores and linear regression analysis are therefore calculated from the H^+ ion concentration. The table of results for pH is for information only.

3. Instructions for use

Please refer to the accompanying documents for full Instructions for Use for both Blood Gas and Co-oximetry vials.

4. Method evaluation – Annual Tonometrol study.

In addition to the monthly aqueous Scheme, WEQAS undertakes an additional annual assessment of instrument accuracy using freshly tonometered bovine blood. WEQAS has identified a range of analysers with improved analytical performance (bias) when using freshly tonometered bovine blood (Tonometrol) compared with aqueous material.

Results of the last Study undertaken is available on: http://www.weqas.com/resources

Please type 'Tonometrol' into the keywords field (no area or category needs to be entered), and click 'search'.

The matrix effects of aqueous samples were clearly identified in these studies. There are therefore obvious advantages in using the freshly tonometered material:

It exhibits similar properties to fresh patient samples in that it contains protein and haemoglobin, giving identical Hb saturation curve for O_2 and Total O_2 content. The material is very easy to use with no reconstitution requirements.

4.1 Matrix effect of aqueous material

Where a potential matrix effect has been identified with the aqueous material, participants should compare their results with the instrument group. Each type of instrument is now uniquely identified in the WEQAS database. Instrument performance data is available for all instruments as part of the monthly report. However the calculation of the SDI score will require a minimum number of 8 participants. The overall mean will be used for scoring if the number is less than 8.

WEQAS will continue to distribute the freshly tonometered haemolysate material on a yearly basis to monitor overall performance and bias.

4.2 Instructions for use - Tonometrol

Due to the limited stability of the fresh haemolysate, participants should analyse the sample within 48 hours of dispatch (preferably the same day as they received it). If immediate analysis is not possible please refrigerate the sample on arrival, bringing the sample to room temperature immediately prior to analysis (i.e. treat in a similar way to fresh whole blood samples transported on ice to the laboratory). The sample should then be mixed gently before analysis.

5. References

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3. Thomas MA. A national EQA programme for Blood Gas/ Co-oximetry - a 3-year experience. IFCC Proceedings of the 17th International Symposium, The Confluence of Critical Care Analysis and Near Patient Testing, France, 1998; 298-314
4. Burnett RW. Matrix effects in blood gas proficiency testing. Arch Pathol Lab With 1993: 117:365-368
5. Thomas MA. An evaluation of the performance of Blood Gas analysis in the UK using tonometered haemolysate material. Clin Chim Acta, 2001: 307; 125-133
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10. Van Kampen EJ, Zijlstra WG. Standardisation of haemoglobinometry. II. The haemoglobin cyanide method. Clin Chim Acta 1961; 6: 538-544
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