



Letter to the Editor

Analytical performance assessment of a novel cartridge-based blood gas analyzer



This letter is in response to an article by E. Aloisio et al. published in *Clinical Biochemistry* [1] regarding analytical performance of the GEM® Premier™ 5000. The authors evaluated analyzer imprecision by assessing daily quality control (QC, Liquichek™ Control Level 2, Bio-Rad Laboratories, Irvine, CA) and compared results to data obtained a year earlier from the GEM Premier 4000. The authors concluded that GEM Premier 5000 CVs were higher when compared with those obtained from the GEM Premier 4000, and previously published data [2], particularly for pO₂ and pCO₂. However, our investigation concludes that—as may often occur when analyzing external aqueous QC materials—pre-analytical sample handling is the source of high CVs.

The authors' assessment of the imprecision of GEM Premier 5000 is in sharp contrast to several published studies that have shown significantly lower CV values [2,3]. To determine the root cause for this discrepancy, we contacted the authors and requested the original data for evaluation. Our analysis of the aqueous QC data verified the reported imprecision; however, we also made several observations that raised questions about the reliability of the results and conclusions.

5 Process Control Solutions (PCSs) in the GEM PAK continuously monitor the quality of the GEM Premier 5000. PCSs D and E have analytical values similar to those tested in the evaluation. PCSs follow the same pathway as a patient sample or external QC ampule. Since the internal PCSs are introduced automatically, variabilities from personnel sample-handling are eliminated [4].

Table 1a summarizes the performance of PCS D and E from the

cartridges used during the evaluation. The CVs for the PCSs were similar to other publications [5] and were significantly lower than those reported in Aloisio et al. These results confirm that the analyzer in question was performing according to manufacturer specifications and the cause for high CVs for the pO₂ and pCO₂ was likely due to pre-analytical factors. For all other parameters, the differences in CVs were statistically insignificant (pH [$p = 0.988$] and Lactate [$p = 0.759$]) and/or within system precision requirements (e.g iCa) as shown in table 1a [5]. HCO₃⁻ is a parameter calculated from pH and pCO₂ values, which are already included in the discussion and same conclusion can be applied.

Another indication of potential pre-analytical issues from the Aloisio et al. data comes from the bimodal distribution of pO₂ measurements (Fig. 1b), which was observed in all tested cartridges. The higher distribution mode, highlighted by the dashed circle, is a typical signature of ampule exposure to air [4]. A much tighter pO₂ distribution of external QC with a similar pO₂ target value is shown in the figure for comparison [5].

In conclusion, analysis of the data obtained from the Aloisio et al. study confirms that the GEM Premier 5000 analyzer was performing within specifications and the higher CV values for aqueous external controls for pO₂ and pCO₂ were likely caused by pre-analytical factors. For accurate pO₂ and pCO₂ measurements on aqueous quality controls, follow recommendations specified in the manufacturer product insert to minimize exposure to air after opening the ampule.

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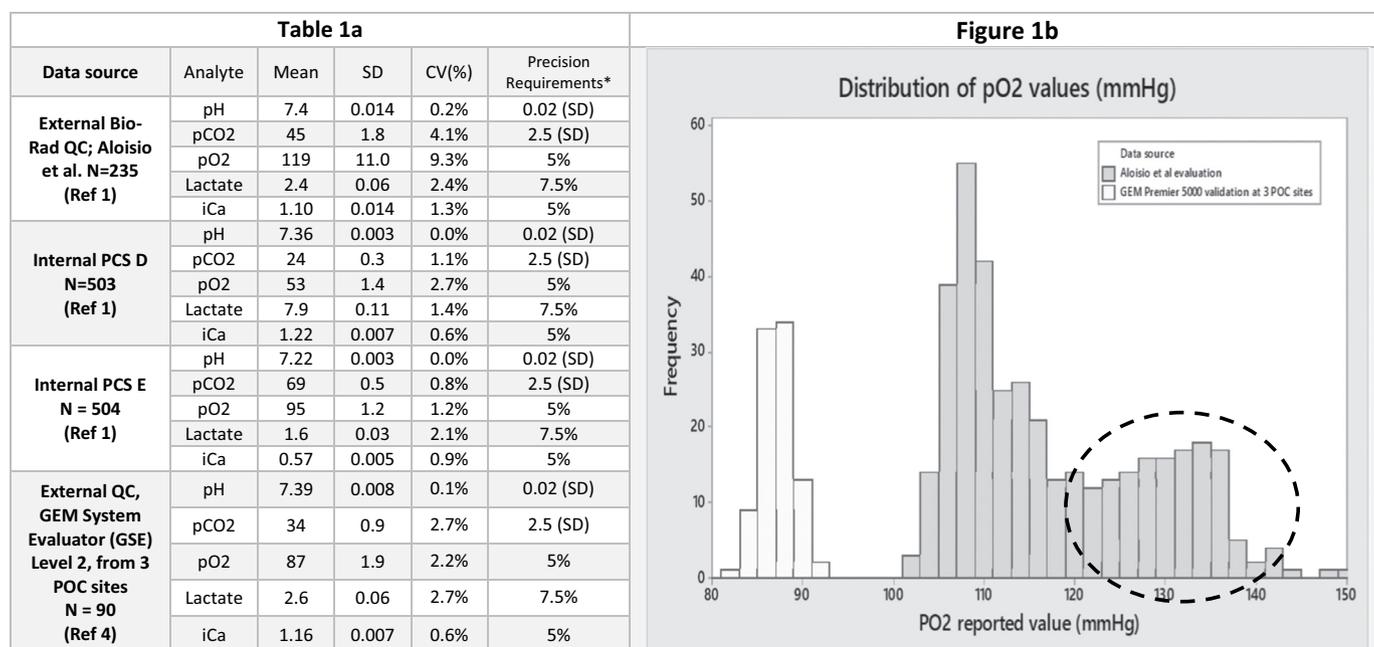


Fig. 1. Comparison of GEM Premier 5000 precision data on internal and external controls (1a) and comparison of pO₂ distribution of external controls on the GEM Premier 5000 (1b). Data highlighted in dashed circle represents high pO₂ measurements from pre-analytical air contamination.*.

References

- [1] E. Aloisio, A. Carnevale, A. Dolci, M. Panteghini, Novel generation of laboratory instruments should not worsen analytical quality: the care of GEM Premier 5000, *Clin. Biochem.* 58 (2018) 128–130.
- [2] M. Oyaert, T. Van Maerken, S. Bridts, Analytical and pre-analytical performance characteristics of a novel cartridge-type blood gas analyzer for point-of-care and laboratory testing, *Clin. Biochem.* 53 (2018) 116–126.
- [3] A. Randazzo, J. De Marchin, Evaluation of the precision performance on the GEM premier 5000 at CHR Citadelle (Belgium), 70th AACC Annual Scientific Meeting Abstracts, 2018, p. B-347.
- [4] L. Dukić, L. Milevoj, A. Dorotić, A. Baršić, Blood gas testing and related measurements: National recommendations on behalf of the Croatian society of medical biochemistry and laboratory medicine, *Biochem Med (Zagreb)* 26 (2016) 318–336.
- [5] FDA 510(K) Premarket Notification: K160412 (pH, pCO₂, pO₂), K160225 (Sodium, Potassium, Chloride, Ionized Calcium) and K160402 (Glucose, Lactate and Total Bilirubin).

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