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Letter to the Editor

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

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To the Editor,

We thank Cervera et al. for commenting our article published in this journal [1]. They pointed out that our GEM Premier 5000 (GP5000) analyzers performed within the manufacturer's specifications, according to data derived from the Internal Process Control Solutions (IPCS). However, this does not mean that the system imprecision is acceptable for its clinical use. Firstly, the use of IPCS data does not consider some sources of variability affecting clinical samples, e.g. sampling variability. Secondly, to correctly estimate imprecision a control material from a third-party independent source, i.e. not provided by manufacturer of the measuring system, must be used. This material should also be different from the control material used for checking the system alignment. Therefore, no conclusions about the imprecision on clinical sample measurement can be derived from IPCS data. More importantly, the analytical performance of laboratory tests, to be fit-for-purpose, should meet the performance specifications defined according to the models described by the 1st EFLM Strategic Conference [2]. On this note, the GP5000 imprecision for partial oxygen pressure (pO_2) and ionized calcium ($_iCa^{2+}$) on whole blood samples reported in the quoted FDA premarket notification documents (although obtained in a period of only five days) quite often did not reach the specifications for desirable CV of 1.6% for pO_2 and 0.9% for $_iCa^{2+}$, respectively.

Although we used the third-party control material strictly according to the manufacturer's recommendation, we agree with the authors that the absolute imprecision performance for pO_2 obtained in our study could have been partly affected by air contamination of the aqueous material. However, this preanalytical issue, if present, affected in the same way the performance of both GP5000 and GEM Premier 4000 (GP4000) analyzers in the two evaluated periods, therefore not influencing the comparison of the performances of two platform generations.

As already stated in our article [3], an ad-hoc experimental protocol performed in standardized conditions and in a short period of time portrays an optimistic estimate of imprecision than determined in clinical practice. Table 1 compares the protocol characteristics of the studies mentioned by Cervera et al. [1]. It is evident that the better imprecision reported by other authors [4,5] can be strongly dependent on the study conditions and, mostly, on the limited study time span. Only a long-term study, spanning over a period of months like ours, can accurately estimate analytical performance, as it most likely covers all relevant sources of variability, such as variations in measuring conditions, different lots of cartridges and operator turnover.

Regardless of all above, the authors have fully ignored the key message of our study, i.e., the worsening of analytical performance for some analytes between the two platform generations. Particularly, for $_iCa^{2+}$, the average CV went from 0.8% on GP4000, which is within desirable imprecision derived from the biological variability of the analyte, to 1.3% on GP5000, which struggles to reach the minimum quality goal. It happened worse for partial carbon dioxide pressure (pCO_2) for which GP5000 was unable to fulfill even the minimum criteria, while GP4000 was well inside them.

Table 1
Comparison of study protocols evaluating the imprecision of GEM Premier 5000.

Authors	Protocol	Study length	Control material	Material matrix
Aloisio et al. [3]	Daily random assessment	5 months	Liquichek Blood Gas Plus EGL (Bio-Rad)	Buffered aqueous solution
Oyaert et al. [4]	CLSI EP5-A3	20 days	GEM System Evaluator (Werfen)	Buffered aqueous solution
Randazzo et al. [5]	Two runs per day and 3 replicates per run	6 days	RNA Medical QC	Buffered aqueous solution

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