**Validation of 24 blood gas analyzers, GEM 5000 Premier**

R. Gadisseur 1, G. Musso 1, L. Vranken, E. Cavalier 1

*1 Clinical Chemistry Department, University Hospital of Liège, Liège, Belgium*

Introduction: Point-of-care blood gas test results may help to take therapeutic decision by their immediate impact on patient care. Recently, a novel cartridge-type blood gas analyzer, the GEM Premier 5000 (IL-Werfen) was commercialized and 24 analyzers were installed at the University Hospital of Liège. One of them was installed in the main central laboratory, the 23 other ones were installed into 19 patient care units. Before the implementation, we evaluated the analytical performance of all the 24 GEM Premier 5000, for the determination of whole blood pH, pCO2 and pO2, electrolytes (Na+, K+, Cl−), ionized calcium (iCa2+), glucose, lactate and co-oximetry parameters ((total hemoglobin (tHb), oxyhemoglobin (O2Hb), carboxyhemoglobin (COHb), methemoglobin (metHb), deoxyhemoglobin (HHb)).

Method: First, we evaluated the performance of the GEM Premier 5000 dedicated to the central lab, so-called “*referent analyzer*”, with 3 levels of External Quality Controls material (EQC RNA Medicals). CLSI EP5 recommends 2 replicates per run, 1 or 2 runs per day, for a minimum of 20 days. Nevertheless, we analyzed the 3 levels of EQC, 2 replicates per run, 2 runs per day during 5 consecutive days. Afterwards, on the whole 24 GEM Premier 5000, we analyzed aqueous QC material (Werfen GEM System Evaluator, level 1-2), 3 replicates within a single run, once per day, during 5 consecutive days. We determined the manufacturer's claim for Within-Run and Total precisions for each. Co-oxymetry parameters were not evaluated on 4 analyzers. Then, we compared the all 23 analyzers to the “*referent analyzer”* of the central lab. Therefore, for each parameter, we showed in a Youden diagram all the results obtained by 23 analyzers. The position of the acceptance ranges were shown graphically using the specifications for Acceptable(%) Root Mean Standard Deviation (RMSD) proposed by the German Guidelines for Quality (RILIBAK) for whole blood parameter, for different ranges of parameters.

Results: The results showed a good correlation between analyzers excepted for some parameters. Lactate and MetHb: level 2 were often over-estimated when compared to “Reference Analyzer”. It could be explained by the fact that this IQC level contains very low Lactate and MetHb rates. The pO2 level2: some results were over estimated (random errors >< cassette reagents >< low values). The pO2 level1: over-estimated with 8 analyzers letting us think that the cassette reagent of our “Reference Analyzer” had a bias in the lower range.

Conclusion: Performance evaluation of a large cluster of Blood Gas Analyzers is always a challenge for a Hospital. Accreditation is one of the main goal in each Belgian laboratory. Hospital Accreditation is also discussed in Belgium. This study shows an interesting approach to validate Blood Gas Analyzers for highlighting data. Based on our study results, we estimated that the evaluated instrument are a suitable blood gas analyzer for both POCT and laboratory use.

