MATERIALS AND METHOD

The study evaluation was conducted from October 2014 to January 2015 involving 40 samples taken from patients hospitalized in Intensive Care Unit, Sunway Medical Centre; it took us about four months to complete the evaluation in order to collect samples covering all range of concentrations from low, normal and high for the selected parameters.

The analyzers used in this study are as stated below: 1. EPOC – Blood Gas Analyzer 2. i-STAT – Blood Gas Analyzer 3. Architect ci8200 Integrated System 4. Cell-Dyn (CD) Sapphire Haematology System

At the core of the study was the Sigma-Metric performance of the selected parameters such as Sodium, Potassium, Glucose and Hemoglobin carried out in the two different portable blood gas analyzers such as EPOC and i-STAT at ICU against the laboratory core analyzers, Architect ci8200 and CD Sapphire.

RESULTS

The bias between the old and new level is the absolute value of the difference between New level = 140.6

As for the slope of regression, Sodium, Potassium, Glucose and Hemoglobin showed a correlation coefficient of more than 0.900 when compared to the main lab core analyzers. The regression equation used to calculate the bias value at the quality control mean level. The bias value is required to calculate the sigma-metric performance of the assays.

Table 3: Summary of the correlation coefficient, slope and Y-intercept for the four assays calculated by using Passing-Bablok regression

CONCLUSION

A sigma performance of 3.0 is the minimum requirement for routine use of any assays and any assays with a sigma metric of 6.0 and above considered world class quality. This study enables us to understand the limitations of each assay either as a poor performing one or world class quality. The blood gas analyzers and core laboratory analyzers showed variable sigma performances and not all of the assays met the minimum performance goal of 3.0. We need to understand the situation patients are faced with as of today and how to deal with the problem.

The emphasis on speed test results has brought the medical world to focus on Point of Care testing devices at patient bedside. For one decade, it has been adopted even in service industries such as healthcare institutions. Medical Laboratories can use the sigma-metric to make decisions about method quality when a new analytical system is in place. In addition to that we are able to show a sigma quality throughout the lifetime of the system2.

Variability of test process depends on the precision and accuracy of the measurement procedure. The analytical measurement process involves in measuring the variation to sodium, potassium, glucose and sigma-metric of the system1. It is crucial to determine the precision and accuracy of any measurement system prior to selecting it for use in the institutions.

As seen in the table above some of the methods do not meet the Ricos Database desirable specifications for precision and bias. As we know the goals are quite tight and not practically achievable by any of the instruments therefore we need to consider on choosing a more practical set of quality goals, thus the Laboratory decided to choose CLIA Proficiency Testing criteria as the total allowable error for this study instead of Ricos goals.

The bias between the old and new level is the absolute value of the difference between New level = 139.6 mmol.

The visual assessment of each instruments by assays are demonstrated using the Normalized Sigma-Metric Decision Chart. For assays that has a value of Sigma performance lower than three such as EPOC-Glucose, EPOC-Hemoglobin, i-STAT-Hemoglobin and Architect ci8200, Sodium requires closer monitoring by increasing the frequency of quality control runs.