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Analytical Performance of Cobas C 8000 Analyzer Based on Sigma Metrics

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Abstract : Introduction: Six-sigma is a metric that quantifies the performance of processes as a rate of Defects-Per-Million Opportunities. Sigma methodology can be applied in chemical pathology laboratory for evaluating process performance with evidence for process improvement in quality assurance program. In the laboratory, these methods have been used to improve the timeliness of troubleshooting, reduce the cost and frequency of quality control and minimize pre and post-analytical errors. Aim: The aim of this study is to evaluate the sigma values of the Cobas 8000 analyzer based on the minimum requirement of the specification. Methodology: Twenty-one analytes were chosen in this study. The analytes were alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), Amylase, aspartate transaminase (AST), total bilirubin, calcium, chloride, cholesterol, HDL-cholesterol, creatinine, creatinine kinase, glucose, lactate dehydrogenase (LDH), magnesium, potassium, protein, sodium, triglyceride, uric acid and urea. Total error was obtained from Clinical Laboratory Improvement Amendments (CLIA). The Bias was calculated from end cycle report of Royal College of Pathologists of Australasia (RCPA) cycle from July to December 2016 and coefficient variation (CV) from six-month internal quality control (IQC). The sigma was calculated based on the formula :Sigma = (Total Error - Bias) / CV. The analytical performance was evaluated based on the sigma, sigma > 6 is world class, sigma > 5 is excellent, sigma > 4 is good and sigma < 4 is satisfactory and sigma < 3 is poor performance. Results: Based on the calculation, we found that, 96% are world class (ALT, albumin, ALP, amylase, AST, total bilirubin, cholesterol, HDL-cholesterol, creatinine, creatinine kinase, glucose, LDH, magnesium, potassium, triglyceride and uric acid. 14% are excellent (calcium, protein and urea), and 10% (chloride and sodium) require more frequent IQC performed per day. Conclusion: Based on this study, we found that IQC should be performed frequently for only Chloride and Sodium to ensure accurate and reliable analysis for patient management.

Keywords : sigma matrics, analytical performance, total error, bias
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