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Evaluation of Clinical Chemistry Assays of Deficiency Anemias Basic Profile using Sigma Metrics in a Clinical Laboratory in Brazil

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Abstract:
Introduction: Anemia affects about 2 billion people globally, being one of the most relevant problems in developing countries, such as Brazil. Anemia is characterized by a low concentration of hemoglobin in the blood and a drop in red blood cells and hematocrit counts, however, these parameters occasionally show normal levels in patients with hemoglobin depletion. According to the 2006 National Demography and Health Survey (NDHS), iron-deficiency anemia reaches 20.9% among children under 5 years old, 24.1% in children under 2 years old, and 29.4% of fertile women. The authors of this study aimed to analyze Iron (Iron), Transferrin (Trf), Total Iron Binding Capacity (TIBIC), Ferritin (Fer), Folate (FO) and Vitamin B12 (VB12) assays using Sigma Metrics on Atellica CH and Atellica IM analyzer, to evaluate the performance of these parameters in a large laboratory in São Paulo, Brazil. **Methods:** The precision evaluation and bias estimation by peer group was performed through the repeatability study ($\%CV_R$) and within-laboratory precision ($\%CV_{WL}$), according to EP15-A3, with a total of 25 samples per QC. The evaluation criteria was based on the comparison of the coefficient of variation obtained with the manufacturer and Total Allowable Error (TEa) specifications. Comparison studies were performed for TIBIC on the Atellica CH and AU 5800 Beckman Coulter Analyzers and for Ferritin, Folate and VB12 on the Atellica IM and Abbott Architect Analyzers according to EP09 using, at least, 50 serum samples. In the Sigma metrics evaluation, precision and bias components were used for each level of QC. **Results**: The precision results agree with the analytical quality specifications. The CV_R obtained was 0.6% to 2.7% and CV_{WL} was 0.6% to 3.6%. Using the TEa based on the Biological Variation table, 8 of 10 results showed 6 sigma performance (world class) and 2 of 10 showed sigma between 3 and 5.9 (good). Using RCPA as reference, 4 of 10 results showed 6 sigma and 6 of 10 with sigma performance between 3 and 5.9 (good). **Conclusion**: All assays tested on the Atellica CH Analyzer have demonstrated acceptable results of precision study (consistent with analytical quality specifications) and sigma metrics, which can provide a basis for understanding the performance of the Atellica Solution Assays. Despite conducting the study of sigma metrics in this work, it is worth mentioning that there is still no consensus on the appropriate source of TEa and how the bias should be calculated or what is the relevant analyte concentration for a given assay, which makes sigma metrics results of complex interpretation. However, these results generate confidence to use Atellica Solution Assays after implementation. *Siemens Healthineers supported the studies by providing systems, and reagents.*
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