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Validation of the lipid profile on the Atellica Analyzer: New Quality Control Methodologies Implementation and Performance Evaluation of the Assays

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Abstract:

Background: The reduction of malnutrition and the increase in overweight and obesity in all age groups favored the appearance of chronic non-communicable diseases (CNCD), especially cardiovascular diseases. Dyslipidemia is one of these diseases and one of the main risk factors for atherosclerotic cardiovascular diseases. Fundamentally, they are diagnosed and phenotyped by laboratory determinations, therefore, the concern of all clinical laboratories is to release results with the maximum possible accuracy considering the best quality control management tools and performance of adopted methods. Sigma metrics have proven to be a powerful tool for objective and quantitative performance evaluation of tests and instruments. The objective of this study was to use sigma metrics to validate the lipid profile assays on the Atellica CH Siemens Healthineers platform in a large laboratory operating in Brazil and to create a scientific basis por planning the appropriate quality control strategy to assess these parameters performance. **Methods:** For the Cholesterol (Chol), HDL, LDL and Triglycerides (Trig) assays on the Atellica CH 1600 Analyzer, the precision and bias estimation peer group evaluation was performed by the repeatability study (%CV_R) and within-laboratory precision (%CV_{WL}), with 25 replicates total per QC sample for each assay. Method comparison studies were performed with the Atellica CH and AU 5800 Beckman Coulter assays according to EP09, using 50 serum samples that covered the entire linearity range. For the evaluation of sigma metrics, different goals of the total allowable error (TEa) were used, such as Ricos, RiliBÄEK, Biological Variation 2014 (VB2014), EFLM and CLIA. **Results**: The precision results are in agreement with the analytical quality specifications, with CV_{WL} of 1.9% to 1.4% and CV_R of 0.5% to 2.1%. For Chol and Trig, which have specifications in all the references mentioned, all results were greater than 6 sigma. Using the analytical quality specification of Biological Variation Ricos, an average sigma of 9.73 for Chol and 16.22 for Trig was observed, while using EFLM and CLIA, the mean sigma was 10.06 and 10.84 for Chol and 17.56 and 15.55 for Trig, respectively, all 6 sigma. Depending on the assay, the choice of TEa specification generates different results, as in the case of cholesterol with an average sigma of 10.84 using CLIA, and 14.17 using RiliBÄEK. The LDL and HDL assays were evaluated using the BV2014, one of the only references with data for both lipoproteins. All results obtained sigma above 3, ranging from 3.70 to 5.81 (good).**Conclusion**: The tests demonstrated acceptable results of precision and sigma metrics. There is still no consensus on the appropriate source of TEa, which makes any sigma result complex to interpret. Thus, it is important to know the performance of each test to apply the most appropriate reference. Once the analyzer is running the tests routinely, these metrics will be evaluated periodically, observing the use of more realistic criteria to achieve the best performance the Atellica CH assays can offer. **Siemens Healthineers supported the studies by providing systems, and reagents.*

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