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Analytical performance assessment of Atellica Solution thyroid assays using sigma metrics

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Abstract:

Background: Thyroid dysfunctions can happen at any stage of life, impairing the regulation of the function of important organs such as the heart, brain, liver and kidneys. With the increase in life expectancy and the number of elderly people, whose prevalence of thyroid dysfunction diseases appears between 2 to 4% of individuals over 65 years and in 0.5 to 1% of the general population. Several factors are involved in the genesis of thyroid dysfunctions, among which are the autoimmune mechanisms, genetic factors related to the HLA system and environmental factors. Reinforcing that, for an adequate diagnosis and monitoring of these diseases, laboratory tests are essential. In this scenario, the authors of this study aimed to validate the performance of the main assays of the thyroid profile in a large laboratory operating in Brazil. We apply Sigma's metric measures to assess the Atellica Immunoassay platform, in order to propose a methodological implementation plan in this company and compare to similar studies. **Methods**: For the assays Thyroid Stimulating Hormone 3-Ultra (TSH), Total Thyroxine (T4), Total Triiodothyronine (T3), Free Triiodothyronine (FT3) and Free Thyroxine (FT4) on the Atellica IM 1600 Siemens Healthineers Analyzer, the evaluation of the verification of the imprecision and estimation of bias by peer group were performed by the within-run imprecision($\%CV_R$) and within-laboratory imprecision ($\%CV_{WL}$) with a total of 25 replicates per QC sample for each assay. Method comparison studies were performed between the Atellica IM and Architect Abbott assays according to EP09, using a minimum of 40 serum samples that covered the entire assay linearity range. For the evaluation of sigma metrics, TEa goals from RiliBÄK was used as a reference. **Results**: The imprecision study agree with the specifications of the analytical quality. The $\%CV_R$ was 0.962% to 3.006%, $\%CV_{WL}$ was 1.70% to 3,90% and the bias was 0.41% to 10.43%. All QC levels for all tests were higher than 3 Sigma, with 7 out of 10 levels were 6 Sigma or higher (world class) and 3 out of 10 levels were 4 and 5 Sigma (good). **Conclusion**: All assays tested on the Atellica IM Analyzer demonstrated consistent results of imprecision, bias and Sigma, according to the quality specifications. 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 ETa which makes any result of the Sigma metric calculations complex to interpret. Our conclusion demonstrates that it is necessary know the performance of each assay and apply more realistic ETa before implement the periodic evaluation of Sigma metrics.*Siemens Healthineers supported the studies by providing systems, and reagents.*

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