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Comparison of five automated immunoassays for measuring thyroglobulin antibodies

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Thyroglobulin antibody (TgAb) measurement is challenging because of the heterogenous nature of the autoantibodies produced, and the lack of standardization between TgAb assays. As a result, method changes between analyzers can be difficult. We evaluated the intra-assay agreement of five different automated TgAb assays, and correlated TgAb results from these assays against other markers of autoimmune thyroid disease and against inhibition of thyroglobulin measurement. 101 clinical samples that had been sent for TgAb analysis were tested using the Tosoh AIA-pack, Abbott Architect, Siemens Centaur, Beckman DxI, and DPC Immulite TgAb assays. Samples were chosen for the study without knowledge of clinical histories, but were selected to provide a range of TgAb values based on the predicate assay in our laboratory (Tosoh AIA pack).
Quantitative results for TgAb varied considerably between assays. However, when samples were classified as “positive” or “negative” for TgAb using the manufacturer recommended cutoffs for each assay, overall agreement between assays was relatively good. 90/101 samples showed agreement in at least 4 of the 5 assays. Overall agreement was highest for Tosoh vs Architect (93%) and DxI vs Immulite (93%) comparisons, but the majority of pairwise comparisons between assays showed >85% concordance in this sample set. The positive call rate varied between assays, with the Centaur assay giving the most positive results (41%), the Tosoh and Architect assays giving an intermediate number (30%) and the DxI and Immulite assays having the fewest positive calls (20%).

The majority of disagreement was observed for “weak-positive” samples where TgAb levels were <4x the assay-specific upper limit of normal.
Although thyroid peroxidase antibody (TPOAb) was present in 40% of the samples, there was no correlation between TPOAb and TgAb results for any of the five TgAb assays tested. However, TgAb-positive samples did show an increased rate of interference with thyroglobulin (Tg) measurements. Both the frequency and magnitude of Tg inhibition were increased in samples that were called TgAb-positive by multiple assays, with 95% of samples that were TgAb positive in >= 4 assays showing diminished recovery of spiked Tg relative to control samples.
In conclusion, we have characterized the relative performance of five automated TgAb assays. Although there was generally good agreement in classifying samples as positive vs negative between these assays, variation does occur, particularly in samples with lower levels of TgAb. Laboratories should be aware of the specific characteristics of their assay in order to appropriately advise clinicians on the significance of such results.

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