00413 Thyroid Stimulating Hormone Receptor Antibody Measurement Using Third Generation High Throughput Immunoassay

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Aims: Measurement of Thyroid Stimulating Hormone Receptor Antibodies (TRAb) is indicated in the diagnosis and management of Graves disease (autoimmune thyroid disease). Our study aims to evaluate the assay performance of the 3rd generation automated Roche Cobas TRAb electrochemiluminescence immunoassay against the Brahms TRAK Human Radioimmunoassay (RIA).

Methodology: Assay performance evaluation of the TRAb assay on the Roche Cobas e602 analyser included imprecision, lower limit of detection, linearity and carry-over studies. Method correlation study using patient serum samples (n=169) was performed between Brahms and Roche Cobas assay. Inter-assay concordance was assessed using the respective manufacturers' reference cut-offs. Reference intervals for TRAb was evaluated on select biochemically stable and thyroid healthy volunteers on Roche Cobas e602 (n=155).

Result: Total imprecision was determined to be ≤6.7% for the Roche assay. The Roche assay measuring range was assessed to be linear to 40 IU/L and had a lower limit of detection of 0.20 IU/L. Results of carry-over studies were insignificant. Method correlation study between Brahms and Roche assays revealed Passing Bablok linear regression slope of 0.87 (95% CI: 0.83 to 0.91) with intercept of -0.03; Spearman's correlation coefficient of 0.95; mean bias (Altman and Bland) of -14.9% (95% CI: -20.6 to -9.2%). Assay concordance for positive/negative results using respective manufacturer's cut-off was assessed to be 90.4% (Cohen's ? = 0.80). The 97.5th upper limit of reference intervals in the local population was derived at 0.82 IU/L.

Conclusion: Although calibrated against the same reference standard 90/672, the assays displayed inter-method variability in quantitative values; assay concordance (? = 0.80) was however substantial. The upper limit of reference interval was also in close agreement with manufacturer values. The Roche TRAb assay with its overall satisfactory analytical performance and rapid assay turnaround time represents an excellent alternative to the Brahms assay and is highly suited for routine clinical use.