Performance characteristics of anti-thyroid peroxidase and anti-thyroglobulin assays on roche cobas E411 immunoassay system

Abstract

Background: Thyroid autoantibodies are measured in the evaluation of patients with thyroid diseases. The clinically important thyroid autoantibodies are anti-thyroid peroxidase (anti-TPO) and anti-thyroglobulin (anti-TG). The aim of this study was to assess the analytical performance of anti-TPO and anti-TG assays on Roche Cobas e411, an automated electrochemiluminescence immunoassay (ECLIA) system. Materials and Methods: The following parameters, imprecision, accuracy and stability were evaluated. Imprecision (within-run and between-run) and accuracy studies were performed using two levels of quality control materials. The stability of samples for anti-TPO and anti-TG measurements were evaluated by calculating the percentage recovery of serum samples stored at different temperatures (4°C, -20°C and -80°C) on day 3 and day 12 of storage. Result: The imprecisions for anti-TPO were between 2.5 to 11.3%. The percentage deviation from the true value was -4.9% and -3.6% for low and high QC, respectively. Anti-TPO showed variable recovery from 92.0% to 119.0% on day 3 and day 12 of storage. For anti-TG, the imprecisions were between 3.0 to 11.5%. The percentage deviation from the true value was 3.5% and 12.7% for low and high QC, respectively. Anti-TG showed variable recovery from 89.8% to 117.0% on day 3 and day 12 of storage. Conclusion: Roche Cobas e411 anti-TPO and anti-TG assays have demonstrated acceptable precision and accuracy. It is recommended that samples for anti-TPO and anti-TG are stored and analysed as per recommended to avoid the effects of storage.

Keyword: Anti-thyroglobulin; Anti-thyroid peroxidase; Electrochemiluminescence immunoassay; Imprecision