Evaluation of the Roche Testosterone II Assay on the MODULAR E170 Analyzer

William E. Owen¹, Mindy L. Rawlins¹, William L. Roberts²
¹ARUP Institute for Clinical and Experimental Pathology, Salt Lake City, Utah
²Department of Pathology, University of Utah Health Sciences Center, Salt Lake City, Utah

Abstract (Revised)

Background: The androgen testosterone is produced in Leydig cells of the testes in males. Normal concentrations of testosterone in females are approximately 3 fold less than in males. In males decreased testosterone may include hypogonadism, hypothyroidism, renal failure, hepatitis or ischemia while elevated testosterone can be caused by malignancy, e.g., testicular or ovarian tumors, exogenous androgens, or sometimes normal variations in puberty, pregnancy, or sudden cessation of steroid therapy. In females increased testosterone can be caused by endogenous or exogenous androgens, acycloguanosine monophosphate (AZT), or by polycystic ovary syndrome, stromal hyperthecosis, ovarian and adrenal tumors, or congenital adrenal hyperplasia.

Methods: The Roche Testo II assay is a MODULAR Analytics E170 module in an automated random access electrochemiluminescence immunoassay. It was evaluated for precision over 21 days using 2 levels of control material and 2 patient pools with testosterone concentrations from 36 to 1031 ng/dL, and method comparison with high-performance liquid chromatography tandem mass spectrometry assay (LC-MS/MS) was also performed in our facility. NIST-certified controls were used while the current generation Roche Testosterone assay (Testo I) was used for the method comparison.

Results: Repeatability (within-run) and within-laboratory imprecision ranged from 1.6 to 2.6 and 2.3 to 5.1 %CV respectively. Passing-Bablok regression was used for method comparison, and included statistics for slope, intercept, r, and SMAD (scaled median absolute deviation), a non-parametric error estimate. Analytic concordance with LC-MS/MS indicates improved specificity for women.

Conclusions: This work was supported by Roche Diagnostics and the ARUP Institute for Clinical and Experimental Pathology.

Results and Discussion

Measurement of testosterone has been shown to have utility in the diagnosis of clinical conditions characterized by increased or decreased concentrations. Published studies have indicated that automated immunoassays for testosterone are accurate for measuring testosterone concentrations seen in healthy men but may give incorrect results for women and children due to poor accuracy and precision at concentrations which are typically below 50 ng/dL. The purpose of our study was to evaluate the performance of a new generation testosterone assay (Testo II) from Roche Diagnostics.

Introduction

Since testosterone measurement has been shown to have utility in the diagnosis of clinical conditions characterized by increased or decreased concentrations, published studies have indicated that automated immunoassays for testosterone are accurate for measuring testosterone concentrations seen in healthy men but may give incorrect results for women and children due to poor accuracy and precision at concentrations which are typically below 50 ng/dL. The purpose of our study was to evaluate the performance of a new generation testosterone assay (Testo II) from Roche Diagnostics.

Methods

The Roche Testosterone II (Testo II) assay, (Roche Diagnostics, Indianapolis, IN) is a fully automated random access electrochemiluminescence immunoassay with chemiluminescent detection. The comparison method is a high-performance liquid chromatography/tandem mass spectrometry assay (LC-MS/MS).

Procedures

Evaluation of the Roche Testosterone II Assay on the MODULAR E170 Analyzer