Multicenter analytical evaluation of a high-sensitivity troponin T assay.

Abstract:
High-sensitivity cardiac troponin assays are being introduced clinically for earlier diagnosis of acute myocardial infarction (AMI). We evaluated the analytical performance of a high-sensitivity cardiac troponin T assay (hscTnT, Roche Diagnostics) in a multicenter, international trial. Three US and 5 European sites evaluated hscTnT on the Modular® Analytics E170, cobas® 6000, Elecsys 2010, and cobas® e 411. Precision, accuracy, reportable range, an inter-laboratory comparison trial, and the 99th percentile of a reference population were assessed. Total imprecision (CVs) were 4.6-36.8% between 3.4 and 10.3 ng/L hscTnT. Assay linearity was up to 10,000 ng/L and the limit of blank and detection were 3 and 5 ng/L, respectively. The 99th percentile reference limit was 14.2 ng/L (n=533). No significant differences between specimen types, assay incubation time, or reagent lots existed. A substantial positive bias (76%) exists between the 4th generation and hscTnT assays at the low end of the measuring range (<50 ng/L). hscTnT serum pool concentrations were within 2SD limits of the mean of means in the comparison trial, indicating comparable results across multiple platforms and laboratories. The Roche hscTnT assay conforms to guideline precision requirements and will likely identify additional patients with
myocardial injury suspicious for AMI.