ANALYTICAL PERFORMANCE OF TOSOH AIA-PACK TROPONIN I ASSAY IN A MULTICENTER EVALUATION

Topic: Cardiac Markers

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Cardiac troponin is the new gold standard for the detection of myocardial necrosis. This necessitates the availability of highly reliable troponin assays. Here we report the results of a multicenter study carried out to evaluate the analytical performance of the new generation AIA-PACK cardiac troponin I (cTnI) assay (Tosoh Bioscience) as determined on the AIA 21, a fully automated, random access immunoassay system. The assay uses two different monoclonal antibodies (19C7 and 16A11) recognizing epitopes that are located in the stable part of cTnI and are not affected by in vivo modifications of the molecule. The study was performed at 6 centers and the protocol consisted of 7 sections: evaluation of calibration stability, detection limit, linearity, imprecision, method comparison, sample stability, and anticoagulant interference. The calibration curve was stable for at least four weeks. The minimum detectable cTnI concentration, defined as the cTnI value corresponding to a signal 3 SD greater than the mean found for 20 replicate measurements of the zero calibrator, was 0.017 µg/L (median value, range: 0.010-0.037, n=9). Dilution of 5 cTnI-rich serum specimens with a cTnI negative pool or with the manufacturer's sample diluting solution showed a highly linear response (r=0.999). For the imprecision study, 8 serum pools were prepared and stored at –80°C until used. Two replicate/specimen x run and one run x day for 20 days, by including two reagent lots and two calibrations, were performed. The following results were obtained (mean cTnI concentration, µg/L, and total CV, calculated using ANOVA method as described in NCCLS EP5-A document): 0.14, CV 11.1%; 0.27, CV 8.7%; 0.49, CV 7.7%; 0.61, CV 8.2%; 1.04, CV 7.0%; 1.58, CV 7.1%; 2.03, CV 6.4%; 5.05, CV 6.8%. 85 specimens (leftover) with cardiac marker tests ordered were analyzed for cTnI on the AIA and the Beckman Access analyzer. Deming regression was used to calculate analytical correlation. Although a good correlation coefficient was observed (0.985), there was a significant bias in the data set, confirming the expected differences in cTnI values due to the lack of international standardization. Serum samples were stable for at least 48 h at ambient temperature (P=0.59), 4 days at 4 °C (P=0.63), and one month at –20°C (P=0.37). In paired samples obtained from 53 patients with myocardial infarction, cTnI concentrations were measured in serum, heparin plasma, and EDTA plasma. cTnI values for heparin and EDTA samples averaged 14.5% (95% confidence interval: 11.1-17.8) and 13.2% (7.9-18.6), respectively, higher than those in serum samples (P <0.001). Being highly sensitive and precise, the AIA cTnI assay is analytically suitable for routine laboratory use.