Troponin test spots MIs earlier, 7/15

July 2015—Beckman Coulter Diagnostics announced the publication of research results in Clinical Biochemistry (Storrow AB, et al. 2015;48:254–259; 260–267) that identify the precise magnitude of change in cardiac troponin required for early diagnosis of a heart attack using its Access AccuTnI+3 troponin I blood test. Beckman's troponin-I assay has been clinically proven through a large, multicenter study and is FDA-cleared and directly aligned with the FDA's October 2010 guidance to manufacturers of troponin tests.

The Access AccuTnI+3 troponin I blood test is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I levels in human serum and plasma using the Access 2 Immunoassay System or UniCel DxI Access Immunoassay System to aid in the diagnosis of myocardial infarction. The precise magnitude of change in the post-market cardiac troponin study data was not evaluated by the FDA as part of the product's 510(k) clearance.

Current clinical guidelines for MI diagnosis require demonstration of a rise and/or fall in troponin values between samples collected in sequence following presentation to the emergency department. However, the guidelines do not quantify what is a clinically significant rise or fall, referred to as "delta" in literature. Without a defined delta, physicians do not have a consistent approach for diagnosing MI.

The results of the study recommend movement away from a percentage-change reading in troponin levels to using an absolute difference by ng/mL change. The study, which consisted of nearly 2,000 patients enrolled at 14 institutions, reports representative diagnostic performance that would be observed in clinical practice for early rule-in and rule-out of heart attacks, and demonstrated that absolute changes (0.01 or 0.02 ng/mL) performed significantly better than relative (percentage) changes at all time intervals after emergency department admission.

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