Representatives of the manufacturer respond:

To the Editor:

All Bayer ACS:180® and ADVIA® Centaur™ system chemiluminescent immunoassays are evaluated during product development for performance characteristics based on specimen collection tube type, anticoagulant, and sample handling. Recommendations are reported in the product inserts in the Specimen Collection and Handling section. The approved specimen types for the ACS:180/ADVIA Centaur CKMB II, Troponin I, and myoglobin assays are serum and heparinized plasma. EDTA plasma was evaluated and is not approved for these tests. In paired specimen studies of the CKMB II assay, we observed ~20% positive bias between heparinized plasma and serum. For the cTnI assay, we also report a negative bias of ~16% for heparinized plasma compared with serum. These biases are reported along with NCCLS sample handling and storage guidelines, which when rigorously followed minimize errors attributable to preanalytical variables (1). The authors are correct in noting that the small variations in the four cases cited for cTnI are well within the 95% confidence intervals of the reported precision of the test (total CV of 6.7% at 1.4 μg/L).

We also clearly recommend that heparinized plasma and serum from the same patient not be used interchangeably in testing, especially when repeat samples and serial profiling are the accepted testing protocol for confirming diagnosis. Good laboratory practice suggests that for an individual patient and study series, sample collection should be uniform regardless of whether there is a bias between sample collection types.

We support the National Academy of Clinical Biochemistry’s guidelines regarding the necessity of serial sampling of several cardiac markers at defined time intervals to most rapidly and accurately rule in or rule out acute coronary syndromes (2). As long as sample handling is the same on repeat testing, the linear relationship (r = 0.995) between serum and heparinized plasma makes any bias inconsequential with regard to obtaining an accurate diagnosis.

References


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