

ORIGINAL ARTICLE

Evaluation of the Chemiluminescence Immunoassays for the Measurement of Troponin I, Myoglobin and CK-MB Using the IMMULITE System in Comparison to Other Measuring Systems

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SUMMARY

We evaluated the chemiluminescence immunoassays for the detection of the cardiac markers troponin I, myoglobin and CK-MB on the IMMULITE System (Diagnostic Products Corporation) in comparison to the same analytes of other companies. The IMMULITE assays are two-site solid phase immunometric assays using a murine monoclonal capture antibody on the solid phase and a polyclonal antibody conjugated with alkaline phosphatase (except CK-MB monoclonal, murine) for detection. Precision was investigated using serum pools with a low, a cutoff and a high concentration of the respective analyte. The results were satisfactory with an intra-assay precision coefficient of variation, CV of 1.7% - 3.2% for troponin I, 2.6% - 5.1% for myoglobin, 2.7% - 5.3% for CK-MB and an interassay precision of 5.1% - 6.9% for troponin I, 5.7% - 7.3% for myoglobin and 3.8% - 8.4% for CK-MB. In linearity studies with various dilution steps, a mean value of 105% was found for troponin I, 103% for myoglobin and 117% for CK-MB. The average recovery was 85% for troponin I, 100% for myoglobin and 95% for CK-MB. The clinical validity of the assays in the diagnosis and therapy of myocardial infarction was investigated in 120 patients who were sent to the hospital with suspected myocardial infarction. Four hours after admission all patients with clinically verified myocardial infarction showed troponin I and troponin T values above the cutoff value. A maximum rate of 32% of the patients (IMMULITE Troponin I) with an instable angina pectoris showed troponin values above the cutoff for myocardial infarction (1.0 µg/L), 4 hours after admission. A cutoff-reduction to 0.2 µg/L for troponin I increased the number of patients to 45%. The negative predictive value was constantly 67%. The results obtained by IMMULITE assays were compared to the Elecsys cardiac assays (Roche Diagnostics) and the AxSYM-cardiac assays (Abbott Diagnostics). The highest correlation ($r = 0.99$) was found for IMMULITE Troponin I (DPC) and Troponin I (Abbott). The Abbott-Troponin I showed the highest diagnostic sensitivity within 4 hours after admission. All compared methods showed a similar diagnostic sensitivity (close to 100%) > 4 hours after admission. For all investigated methods the percentage of discrepant results decreased to a minimum 4 hours after admission. (Clin. Lab. 2002;48:211-221)