Evaluation of an Improved Immunoturbidimetric Assay for Serum C-reactive Protein on a COBAS INTEGRA 400 Analyzer

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SUMMARY

Recent studies have shown that C-reactive protein (CRP) can be used as a prognostic risk marker of cardiovascular disease. This new clinical indication requires accurate and precise measurement of CRP at low concentrations (<5 mg/L). We evaluated the analytical performance of an improved CRP immunoturbidimetric method (CRPLX from Roche Diagnostics) on a COBAS INTEGRA 400 analyzer. The assay is simple and rapid to perform with low sample volume (2.5 μL). The limit of detection is 0.26 mg/L, with a working range extending to 194 mg/L. The method shows low imprecision in the whole dynamic range, with a day-to-day coefficient of variation of 10% at a CRP concentration of 0.66 mg/L. There is no interference by bilirubin, hemoglobin, triglycerides and rheumatoid factor up to high concentrations. It compares well with a high sensitivity nephelometric assay, widely used as reference method, and with a classical turbidimetric assay. We conclude that this CRP assay offers to the clinical laboratory an efficient and reliable alternative to high sensitivity immunoassays in the new CRP applications. (Clin. Lab. 2002;48;313-317)