Study of a High-Sensitivity CRP Assay by Latex-Enhanced Immunonephelometrics on a BN II Analyzer

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Abstract: Recently, owing to the development of a new method to perform high-sensitivity measurements of C-reactive protein levels, chronic inflammation has thus been found to be associated with various disease states. In this study, we assessed the accuracy of this high-sensitivity measurement method in order to evaluate the C-reactive protein levels based on nephelometry using the BN system (Behring) to make an accurate clinical diagnosis of chronic inflammatory disease. This method showed such a high degree of accuracy within-day and between-day, that the CV value was less than 3% at concentrations of around 0.1 mg/dl of CRP and the sensitivity was 0.02 mg/dl. These results were consistent with the criteria established for measuring the predictable factors recognized by the U.S. Food and Drug Administration (FDA). The high-sensitivity measurement of the C-reactive protein levels could thus make it possible to diagnose infectious diseases at an early phase, while also being able to diagnose various inflammatory diseases in chronic states.

Key words: High-sensitivity C-reactive protein, FDA, BN system, Nephelometry, Chronic inflammatory diseases