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PERFORMANCE EVALUATION OF NANOPIA KL-6 ASSAY IN INTERSTITIAL LUNG DISEASES

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Background: KL-6 has been reported to serve as a sensitive marker for monitoring disease activity and predicting the prognosis of interstitial lung diseases (ILD). The aim of the present study was to evaluate the analytical and clinical performance of Nanopia KL-6 assay (Sekisui Medical Co. Ltd. Tokyo, Japan) based on latex-enhanced immunoturbidimetry method.

Methods: From March to October 2016, 260 patients diagnosed with ILD were enrolled in this study. All patients with ILD underwent HRCT and pulmonary function test (PFT). We used 113 samples and 200 samples for disease and healthy control, respectively. The evaluation consisted of determination of the precision, linearity, method comparison with ELISA kit (EIDIA, Tokyo, Japan), sensitivity and specificity and correlation with HRCT findings or PFTs. The HRCT findings were graded on a one to six scale based on the classification system.

Results: The total CV for low and high level quality control materials were below 2% at each concentration. Acceptable linearity was observed in their respective reportable ranges. Correlation analysis of KL-6 indicated that results of the Nanopia KL-6 assay were comparable to ELISA ($r = 0.979$). Using a ROC curve, the optimal cutoff point of KL-6 was 350 U/mL with a sensitivity and specificity of 73.9% and 98.0%, respectively, and the area under the curve was 0.953. Serum KL-6 levels were positively correlated with the extent of involvement, traction bronchiolectasis and ground-glass attenuation on the HRCT. In the comparison of all ILD patients' subgroups, significantly higher levels of KL-6 were determined in the idiopathic pulmonary fibrosis (IPF) or connective tissue diseases-related ILDs (CTD-ILD) than other groups. KL-6 levels were negatively correlated with PFTs. In IPF patients, there were statistically significant correlations with all PFT results, but in nonspecific interstitial pneumonia and hypersensitivity pneumonitis groups, some of the test measurements showed a good correlation with KL-6.

Conclusion: The overall analytical and clinical performance of Nanopia KL-6 assay is acceptable for the monitoring of disease progression in clinical practice. Therefore, KL-6 serves as a useful non-invasive biomarker to assess the disease severity in patients with ILD.

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