

## Quantification of IgG4 concentrations across multiple platforms

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### Background:

Serum IgG4 measurement is part of the comprehensive diagnostic criteria for all IgG4-related diseases (IgG4-RD). The Binding Site Group Limited (TBS) manufactures immunoassays for quantification of serum IgG4 on different platforms. The aim of this study was to compare the measurement of IgG4 concentrations using four different TBS IgG4 immunoassays operated on the TBS Optilite<sup>®</sup>, SPAplus<sup>®</sup> turbidimeters, and the Siemens BNII<sup>™</sup> nephelometer.

### Materials & Methods:

Serum samples were obtained from 10 pancreatic cancer patients, 20 chronic pancreatitis patients and 30 autoimmune pancreatitis (AIP) patients (49:11 MF, median age 67 years, range 37 – 86) diagnosed at Shinshu University Hospital, Japan. The following TBS IgG4 assays were used: Optilite<sup>®</sup> IgG4 assay, Human IgG4 subclass liquid reagent assay for use on the SPAplus<sup>®</sup>, the latex Human IgG4 subclass liquid reagent assay and the antisera human IgG4 subclass liquid reagent assay for the BNII<sup>™</sup>. The antisera kit was used at diagnosis and as reference in this comparison. Serum IgG4 values >1350 mg/L were considered elevated. Correlation between concentrations was assessed using Passing & Bablok analysis and calculating Spearman's correlation coefficient.

### Results:

Correlations to the reference method were: Optilite, slope 0.94,  $R^2 = 0.99$ ; SPAplus<sup>®</sup>, slope 1.13,  $R^2 = 0.99$  and on the BNII latex with antigen excess parameters, slope 1.14,  $R^2 = 0.98$ . Agreement between all platforms was high (90-93%,  $P < 0.0001$ ). The discrepant samples were all borderline samples around 1350 mg/L. Using a cut-off of 1350 mg/L to identify AIP patients the AUC determined in all four assays was high (0.95) and there was no significant differences between the concentrations ( $P = 0.70$ ).

### Conclusions:

Comparing IgG4 measurements using TBS immunoassays developed for different analysers gave good correlation and agreement with regards to sample values and diagnosis. Identification of patients with elevated IgG4 was not significantly different between assays. IgG4 measurements obtained using TBS immunoassays on different analysers for diagnosis and during monitoring of different diseases are therefore comparable.