

## **METHOD FOR ANALYSING AGGREGATES IN ANTIBODY SAMPLES**

### **Field of the Invention**

5     The present invention relates to methods for analysing a sample of immunoglobulins.

### **Background of the Invention**

10     The characterisation of antibodies, such as structural characterisation and physiochemical analysis, is required by developers and producers of antibody based therapeutics. Antibodies produced for therapeutic use are subject to quality control to ensure that the antibodies as produced have necessary binding characteristics and stability. One of the key qualities to be assessed is the extent if any of any aggregation of antibodies for therapeutic use. Such aggregation is detrimental to the overall quality and effectiveness of the antibodies. Previously, size exclusion chromatography (SEC) has been  
15     used to assess the amount of aggregates in an antibody preparation. This is a low throughput method. Improved methods for the quantification of aggregates in an antibody preparation are required.

### **Summary**

20     A cysteine protease enzyme from *Streptococcus pyogenes*, immunoglobulin G-degrading enzyme of *S. pyogenes* (IdeS) has been reported to have the activity of cleaving IgG antibodies to produce Fc and Fab fragments. The present inventors have identified that aggregated antibodies are able to withstand IdeS digestion, and that there is a direct relationship between the amount of aggregated IgG in a sample and the amount of IgG  
25     amenable to digestion by IdeS. Accordingly, the present disclosure is directed to the use of an IdeS polypeptide to quantify the amount of aggregated antibody present in a sample. The use of IdeS provides the opportunity to analyse samples and quantify the amount of aggregates therein using high throughput methods.

30     In one aspect of the present disclosure, there is provided a method for quantifying the amount of IgG antibody aggregate in a sample of IgG immunoglobulin molecules comprising

- (a)     contacting the sample with a IdeS polypeptide under conditions which allow cleavage of an unaggregated IgG antibody,
- (b)     quantifying a cleavage product produced in step (a), and