

**Molecular Biotechnology Programme** 

Uppsala University School of Engineering

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Title (English)

Author

### Development of an immunoassay for detection of IgG aggregates in Gyrolab Bioaffy

Title (Swedish)

Abstract

An immunoassay for detection of IgG aggregates in Gyrolab Bioaffy was developed using dimeric anti-IgG Affibody as capturing reagent and the tetramer form as detecting reagent. The ratio between this assay and a reference assay using the same capturing reagent and a Fab reactive Fab'<sub>2</sub> fragment as detecting reagent was used to indicate the presence of IgG aggregates. IgG samples were heat treated to produce aggregates and the samples were analyzed using size exclusion chromatography to determine the aggregate proportion in the samples. About 3 to 4% aggregates were detectable using this method.

Keywords

Immunoassay, IgG aggregates, therapeutic monoclonal antibodies, size exclusion chromatography, ÄKTApurifier, anti-IgG affibody, Bioaffy 20 HC CD microlaboratory

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