

IGG PURITY ASSAY USING A NEW HIGH RESOLUTION SDS-GEL

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Capillary SDS-Gel electrophoresis of proteins has been an important analytical method used to characterize, monitor process control and provide quality control for the production of immunoglobulins. In this poster we present the development of a new polymer formulation and standardized methodology to assess the purity and heterogeneity of IgG and its isoforms. This methodology provides increased resolution of the IgG isoforms from typical developmental impurities like non-glycosylated heavy chain, and low molecular weight impurities associated with the IgG light chain. The assay includes an artificially engineered IgG control with a fixed percentage of non-glycosylated heavy chain to provide assay suitability determination prior to the analysis of unknowns. All aspects of the methodology from sample preparation to automating data analysis will be discussed.