Abstract

The present study was designed to determine whether an enzyme-linked immunosorbent assay (ELISA) approach is suitable for measuring IgG and IgM antibodies (ABA) to Imprime PGG (Immunoprecise Therapeutics, Vancouver, BC, Canada) in healthy human subjects. The ELISA approach was selected because it is straightforward, rapid, and cost-effective compared to alternative methods. In this study, IgG and IgM ABA were purified from healthy subject serum, using a protein A-Sepharose (Pharmacia, Uppsala, Sweden) affinity chromatography method. The purified IgG and IgM ABA were used as "gold reference standards" in the ELISAs. The ELISA approach was optimized using 1) a standard curve of purified IgG and IgM ABA, 2) an IgG and IgM ABA calibration curve, and 3) a standard ABA recovery assay. The ELISA approach was validated using an inter-assay precision study, an inter-assay imprecision study, and an inter-assay imprecision study. 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