



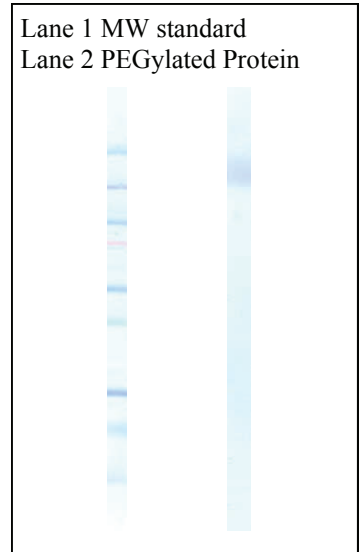
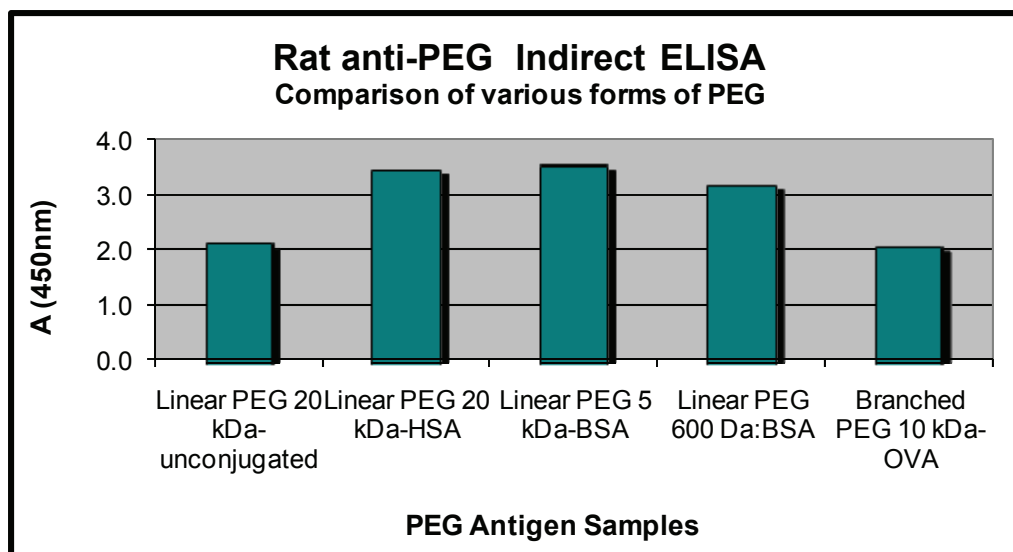
Antibodies to Polyethylene glycol (PEG)

It is an increasingly common practice to enhance the efficacy of drugs or therapeutic agents with the conjugation to PEG. The attachment of PEG to a drug or therapeutic protein increases the *in vivo* half life of the agent by altering the surface of the molecule. The result is improved drug solubility, increased stability, and decreased immunogenicity, resulting in extended circulating life. With such innovation comes the need for new tools to validate, track and improve upon the process. Maine Biotechnology Services has developed two antibodies that recognize all forms of PEG; large, small and branched. There are broad applications for these antibodies in both production and R&D settings. Our PEG antibodies can be a vital tool for propelling therapeutics to market by serving as a positive control anti-drug antibody, measuring clearance of a drug, or simply in a western blot as a QA release confirming PEGylation. Our antibodies serve well as an R&D tool aiding the refinement of the PEGylation process and purification of the resulting proteins by recognizing all forms of PEG.

- **Rat Monoclonal Antibody to PEG**
- **Serve as Positive Controls for Drug Detection Assays**
- **Monoclonal Antibody to PEG**
- **Can be Used for Drug Release Assays by Western Blot**

Technology

Our anti-PEG IgM antibody was developed in a CD rat immunized with 5 kDa PEG conjugated to KLH using the MBS rapid immunization protocol. The fusion resulted in several IgM clones specific for PEG. The strongest clone, as determined by cell culture quality and specific antibody signal to PEG, was selected for subcloning, production and purification. The monoclonal antibody is produced *in vitro* and purified using a proprietary multi-platform protocol. By indirect ELISA, the antibody recognizes linear 20 kDa PEG, linear 5 kDa PEG, linear 600 Da PEG and branched 10 kDa PEG. It also binds to BSA conjugated PEG by western blot.



Technology Continued

Our anti-PEG IgG3 antibody was developed in Balb/c mice immunized with the 5 kDa PEG conjugated to KLH using the MBS rapid immunization protocol. The best performing fusion product was selected using the same criteria as for the IgM for subcloning, production and purification. The monoclonal antibody is produced *in vitro* and purified using protein A. By indirect ELISA, it recognizes linear 20 kDa PEG, linear 5 kDa PEG, and branched 10 kDa PEG. The antibody is currently being evaluated for western blot applications.

