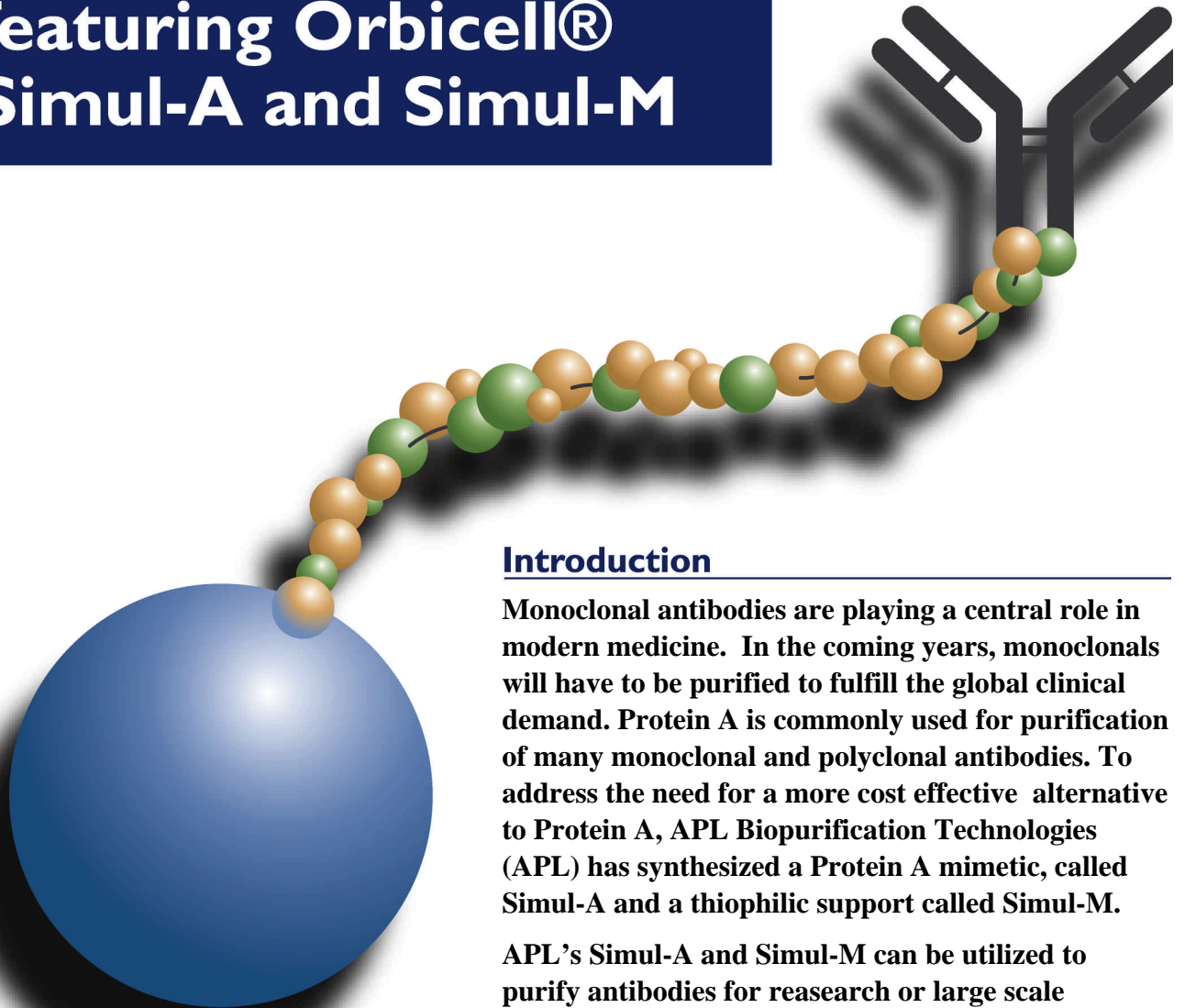


Antibody Purification featuring Orbicell® Simul-A and Simul-M



Introduction

Monoclonal antibodies are playing a central role in modern medicine. In the coming years, monoclonals will have to be purified to fulfill the global clinical demand. Protein A is commonly used for purification of many monoclonal and polyclonal antibodies. To address the need for a more cost effective alternative to Protein A, APL Biopurification Technologies (APL) has synthesized a Protein A mimetic, called Simul-A and a thiophilic support called Simul-M.

APL's Simul-A and Simul-M can be utilized to purify antibodies for research or large scale therapeutics. The surface of APLs small, non-porous cellulose beads (1-3 microns) are grafted with affinity ligands which bind antibodies. The affinity ligands are small, protease resistant organic molecules covalently bonded to the bead surface. Large scale separations can be achieved with continuous centrifugation or tangential flow techniques which separate and purify antibodies in a fraction of time as compared to traditional column chromatography.

Features and Benefits

Small organic affinity ligands are attached to the cellulose support through stable covalent bonds eliminating leaching problems

Affinity ligands are not susceptible to proteolytic cleavage

Loading under saturation conditions ensures high capacity, up to 10% of the antibody weight per dry weight of the sorbent

The non-porous character of the Orbicell® beads minimizes diffusional effects allowing for quicker washing and production of purer end products

Orbicell® bioresins routinely achieve purifications of 85-95%

Orbicell® bioresins can be sterilized by autoclaving.

Orbicell® Simul-A Cellulose Beads 1-3 microns

Capacity and Binding Behavior:

When Orbicell® beads are used in excess, bovine IgG can be stripped from 7% BSA solution to concentrations of 3.2 to 3.8 ug/ml.

Simul-A also purifies polyclonal antibodies from ascites fluid by a method similar to the MoAb listed above.

Representative Examples

- Bound up to 86% of MoAbs isotypes (mouse) adsorbed from dilute (45 ug/ml) tissue culture solutions
- Bound human polyclonal IgG at >50mg/gm beads.

Cleaning and Stability:

Simul-A is compatible with all biological buffers, chaotropic agents, 6M Urea, guanidine hydrochloride etc. Harsh sanitation conditions such as 0.45M NaOH can be applied for cleaning. Orbicell® beads can be made sterile by autoclaving as well.

Reusability:

After 15 cycles no significant loss in performance

Orbicell® Simul-M Cellulose Beads 1-3 microns

Capacity and Binding Behavior:

Very effective in the removal and purification of polyclonal antibodies from human plasma paste extract (Cohn Fraction) or from serum (post DE-52 absorption of contaminants).

Affinity resin binds immunoglobulins at 0.45M Na₂SO₄. They release immunoglobulins at 0.05M sodium acetate, pH 5.

Capacity (static) is greater than 50 mg of polyclonal IgG (from serum) /g of beads. Mild binding and elution conditions appear to be good for maintaining the nativity (avidity for antigen) of the purified antibody.

Representative Examples

- Bound immunoglobulin(s) from goat milk at neutral pH.
- Bound IgA from genetically engineered corn.
- Bound IgY from egg-yolk.

Cleaning and Stability:

Simul-M is compatible with all biological buffers, 6M urea, guanidine hydrochloride, chaotropic agents, etc. Stable in 0.4M NaOH for at least 7 days. Simul-M is autoclavable.

Reusability:

After 15 cycles no significant loss in performance was observed.

