NIDS® DIY Immunogenicity ELISA Kit

ANP offers a complete Do-It-Yourself (DIY) kit for developing a bridging immunogenicity (IM) ELISA. Each kit contains all the reagents to label your biotherapeutic antibody or protein to function as conjugates in a bridging assay and to optimize your assay using HyperBind streptavidin plates, an HRP-labeled detector reagent, colorimetric substrate reagent and stop solution.

The basic design of the bridging IM ELISA is shown in the following figure:

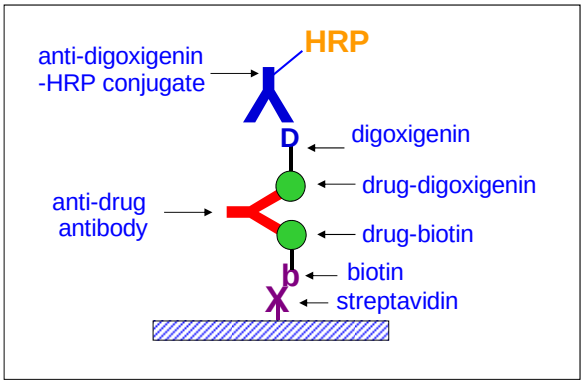

Figure 1. Schematic of the Immunogenicity ELISA

The NIDS® Advantage

The nano-intelligent detection system (NIDS® technology) enables the optimal orientation of coated proteins such as antibodies to impart maximum reactivity. Figure 2 graphically depicts how NIDS ® polymers improve performance of assays compared to conventional coating methods.

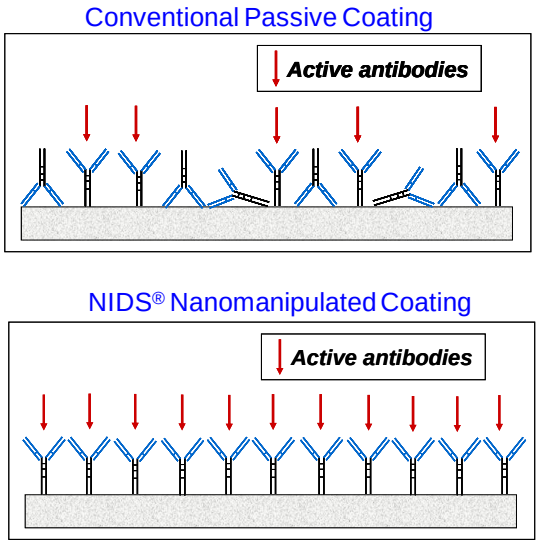

Figure 2. The nano-orientating advantage of the NIDS® technology

Superior ELISA Plate Coating Technology

The NIDS® DIY Immunogenicity ELISA kit exploits the advantages of the nano-orienting capabilities of patented NIDS® polymers. When applied to coating ELISA plates with streptavidin, the NIDS technology in HyperBind ELISA plates confers significantly higher binding efficiency of biotin-labeled proteins and enhances the sensitivity and signal range of sandwich ELISAs. Examples of this are shown in Figures 3 and 4. Figure 3 compares HyperBind plates with commercial plates in direct coating of a biotinylated mouse IgG, which is detected with an anti-mouse-HRP conjugate. Figure 4 compares the performance of HyperBind plates in a sandwich ELISA for mouse IgG using a biotinylated rabbit anti-mouse IgG antibody coated on the plates and an-HRP-labeled goat anti-mouse IgG antibody as the detector reagent.

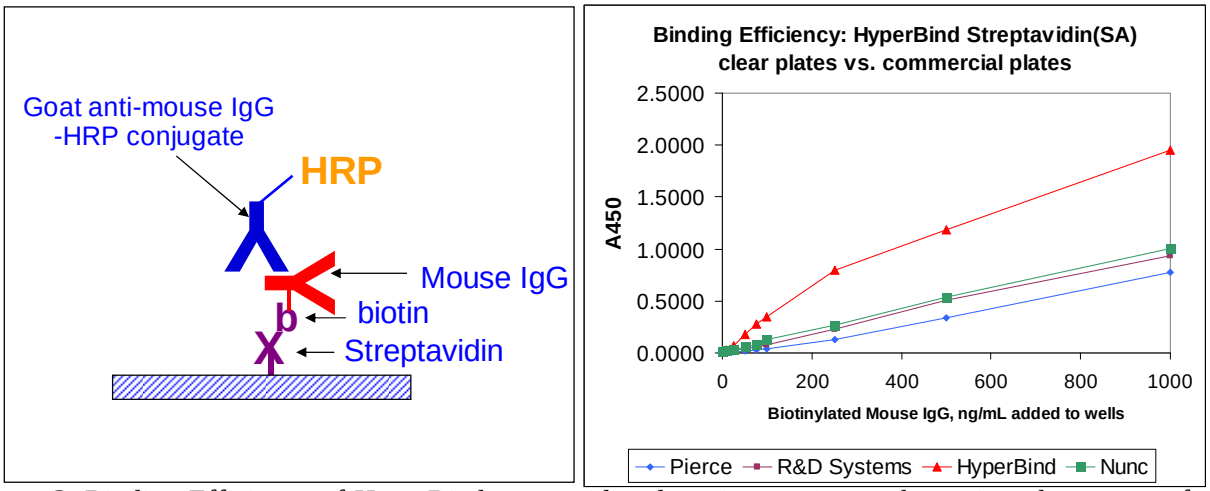

Figure 3. Binding Efficiency of HyperBind streptavidin plates is superior as shown in a direct assay for the detection of biotinylated mouse IgG.

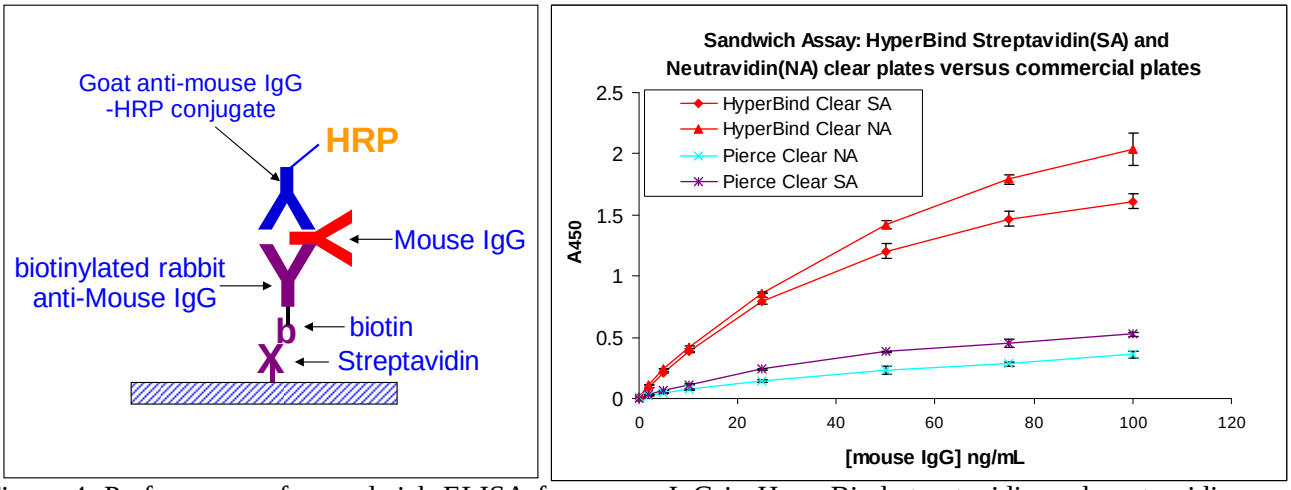

Figure 4. Performance of a sandwich ELISA for mouse IgG in HyperBind streptavidin and neutravidin plates is superior to those obtained with commercial plates.

Optimized Linking Chemistries

Each kit provides proprietary linker reagents for labeling your biotherapeutic drug molecules, one for biotin conjugation and the other for digoxigenin conjugation. These linkers use proprietary polymer structures that have been optimized for immunoassay applications with low charge densities, high water solubilities, and long-term stability of the resulting conjugates. The conjugates prepared with these linkers will generate low background signal and wide signal dynamic range in your assays. Each kit provides a rapid QC test using low nanogram quantities of product to confirm that conjugation with either biotin or digoxigenin has successfully occurred.

Complete Toolbox for Developing Bridging Immunogenicity ELISAs

Each kit provides the following tools for IM ELISA development:

- NIDS® HyperBind Streptavidin –coated clear 96-well ELISA plate
- NIDS® DIY Biotin-2000-NHS Antibody Labeling Kit
- NIDS® DIY Digoxigenin-NHS Antibody Labeling Kit
- HRP anti-Digoxigenin Conjugate Concentrate: Horseradish Peroxidase (HRP)-labeled anti-Digoxigenin mouse monoclonal antibody.
- Tetramethylbenzidene (TMB)/hydrogen peroxide reagent
- 2N Sulfuric Acid Stop Solution

Immunogenicity ELISA Example

ANP has developed a Polyethylene glycol (PEG) Immunogenicity ELISA using the components in the DIY kit. The dose response obtained using a PEG-specific mouse monoclonal IgM positive control antibody with biotinylated and digylated 40 kDa PEG is shown in Figure 5 below:

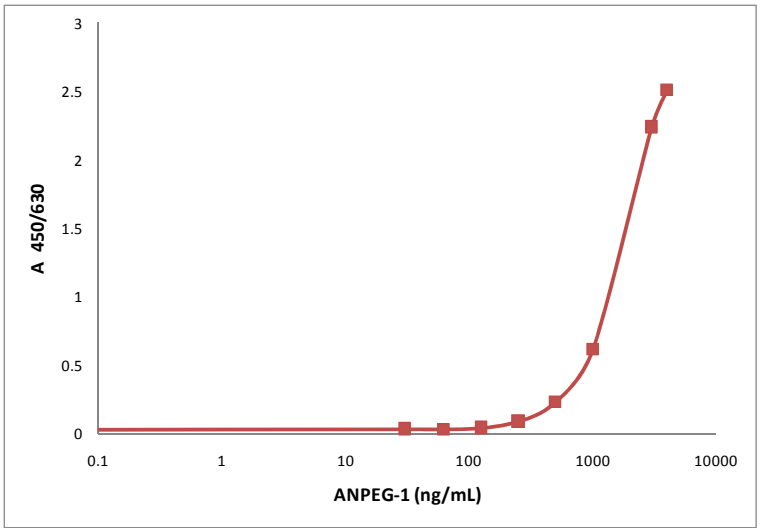

Figure 5. Dose response curve of a PEG Immunogenicity ELISA developed using DIY kit components.