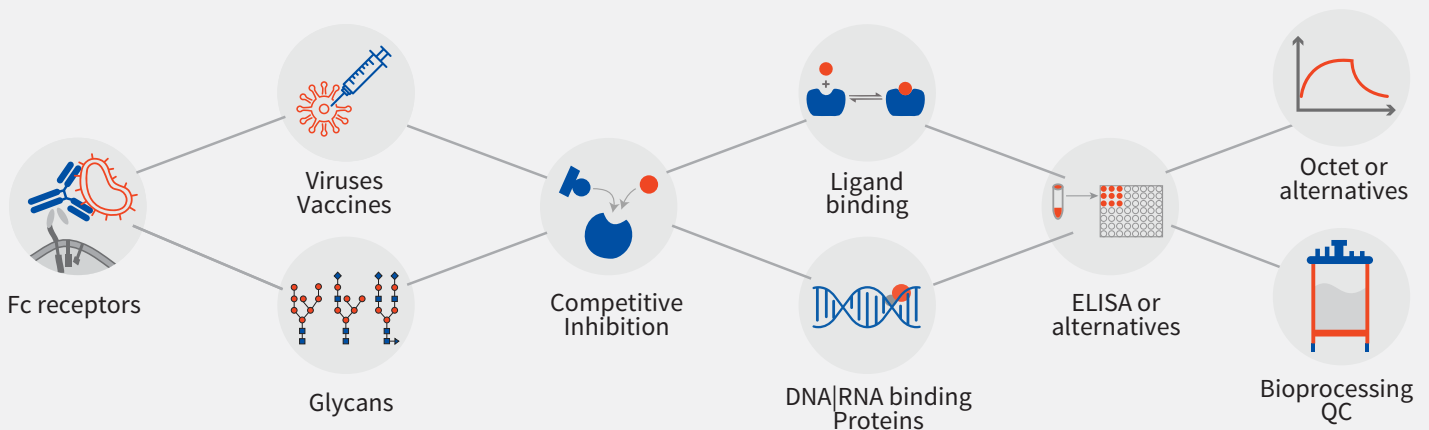


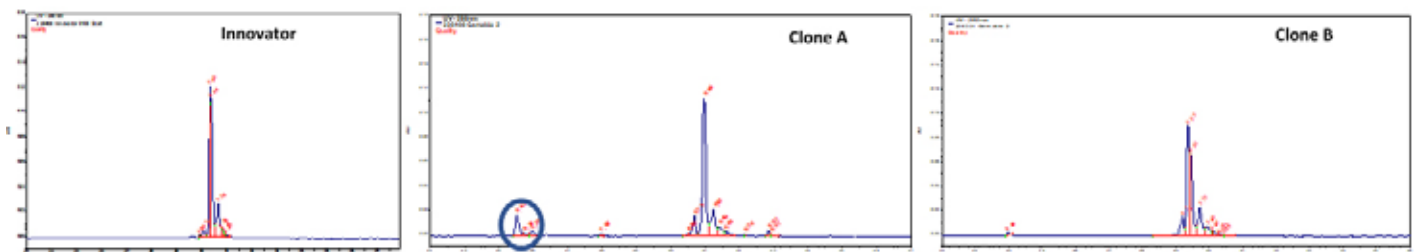
# Rigorous and Comprehensive Analytics to Support Biologics Discovery and Development



Bioanalytical testing is a critical component to all successful drug discovery and development programs. IND-enabling studies require that biotherapeutic proteins, or biologics, undergo rigorous testing to increase the likelihood of being developed into drug products. Using a set of biochemical and biophysical assays, the purity, structural integrity, and chemical stability of potential biotherapeutics are established and used to determine the candidates with favorable profiles to advance or redesign. Aragen Analytics capabilities include CE-SDS, cIEF, SEC-HPLC/MALS, LC/MS, DLS/SLS, LAL, HIC, HILIC, and SPR/BLI.

## Early analytics for selection of Clones:

Incorporation of analytics at an early stage of cell line development accelerates right clone selection, leading to a significant reduction of the project timelines and resource requirements. Employing cIEF to eliminate the undesired basic peak clone (clone A) that do not overlay with the innovator



| PROTEIN ANALYTICS                             | QUALITY ATTRIBUTE              | PLATFORM          |
|---|--------------------------------|-------------------|
| Protein concentration by A280                 | Quantity                       | UV-Vis            |
| A280, A320, Appearance                        | General- Appearance, Trubidity |                   |
| Free-thiol by Ellman's assay                  | Primary Structure - Free thiol |                   |
| Enzyme kinetics ( $k_{cat}$ , $k_{cat}/K_M$ ) | Potency                        |                   |
| N-Glycan profiling by CE                      | Primary Structure - PTMs       | SCIEX PA 800 Plus |
| Charge variants by cIEF                       | Purity - Charge variants       |                   |
| Charge variants by CZE                        | Purity - Charge variants       |                   |
| Size variants (fragments) by CE-SDS           | Purity - Size variants         |                   |



| PROTEIN ANALYTICS  | QUALITY ATTRIBUTE                               | PLATFORM  |
|--|---|---|
| LC-MS Intact Mass (non-reduced, reduced, +/- PNGaseF)      | Primary Structure — MW                          | LC-MS/MS  |
| LC-MS/MS PepMap  | Primary Structure— PTMs, Modifications          | Agilent QTOF attached to nanoflow Chip-Cube or microflow UPLC (ESI) |
| PepMap UV  | Identity  |   |
| N-Glycan profiling by RP-MS or HILIC-MS                    | Primary Structure — PTMs                        |   |
| Glycation by LC-MS/MS                                      | Primary Structure Modifications                 |   |
| Absolute mass of monomer and aggregates                    | MW - Size variants                              | SEC-MALS (Wyatt 18-angle MALS)                                      |
| Tm(Fluorescence), Tagg(SLS),-Size and PDI (DLS) by UNcleTM | Thermal Stability, Higher Order Structure (HOS) | Unchained Labs UNcleTM  |



| PROTEIN ANALYTICS                            | QUALITY ATTRIBUTE              | PLATFORM   |
|--|--------------------------------|--|
| Slab gel IEF                                 | Purity—Charge variants         | Gel Electrophoresis                              |
| SDS-PAGE (non-reduced and reduced)           | Purity —Size variants Identity |  |
| Western blot                                 | Identity                       |  |
| Binding kinetics (kon,koff, KO)              | Potency, Identity              | BioLayer Interferometry (BLI) ForteBio Octet RED |
| FcR and C10, binding                         | Half-life, Safety              |  |
| Protein concentration, antigen binding titer | Quantity                       | or<br>Surface Plasmon Resonance (SPR) Biacore    |
| Epitope binning                              | Epitope characterization       |  |
| Functional blocking                          | Potency Identity               | Molecular Decices SpectraMax                     |
| Yes/No binding                               | Identity                       |  |
| Binding ELISA                                | Potency                        |  |
| HCP ELISA (Cygnus)                           | Safety                         | Charles River EndoSafe                           |
| Residual Protein A/G/L by ELISA              | Safety                         |  |
| Endotoxin by Limulus Amebocyte Lysate (LAL)  | Safety                         |  |
| Bioburden, Sterility Test                    | Safety                         | Culturing  |



Let's begin the Conversation

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