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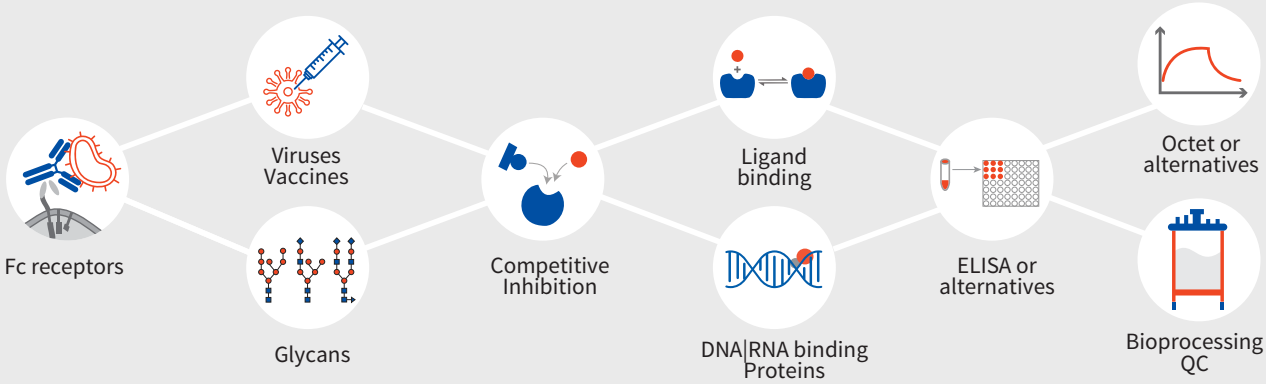
Comprehensive Characterization of Biologics

Biophysical characterization is essential in the development of both innovator biologics and biosimilars. The function, activity, and stability of biologic drugs are often influenced by the physical and biological behavior of proteins. Biophysical analytical techniques play a key role in monitoring and confirming conformational integrity, assessing the folded state of proteins, and understanding peptide interactions that form complex structures. Additionally, studying specific interactions between the drug substance and excipients is crucial, as these can impact protein structure and overall product stability. These techniques are also valuable for analyzing protein degradation and aggregation, which are critical considerations during formulation development, stability studies, and comparability assessments.

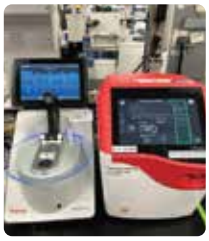
Comprehensive Biologics Characterization



Aragen has established a state-of-the-art analytical laboratory, fully equipped with advanced instrumentation and staffed by highly qualified analytical scientists. Our facility supports comprehensive characterization of biologics, utilizing cutting-edge technologies such as Octet/BLI, Biacore/SPR, UV-Vis, SCIEX/PA800 Plus, LC-MS/Q-ToF, Wyatt/MALS, UNCLE/SLS/DLS, and SpectraMax multimode plate readers for high-throughput analytics. We offer the capability to characterize biologics developed both by clients and those produced in-house at Aragen. Every biologic analyzed undergoes stringent quality control (QC) checks before being shipped to clients.

Biacore T200

Uncle



NanoDrop

Helios (SEC-MALS)

Gel Electrophoresis

Octet/Biacore:

For characterizing antibody epitopes and multiprotein complexes of biological significance - detect presence of specific proteins with minimal interference from complex matrices.

- Binding kinetics (1-3wks)
  - Fc Receptors
  - Ligand binding
  - Competitive inhibition
- FcR and C1q screenings (1-4wks)
- Functional blocking (1-4wks)
- Off-rate ranking (1-4wks)
- Epitope binning (3-4wks)
- Bioprocessing QC
- Antibody Discovery

Characterizations by Mass Spec

- Intact mass (red/non-red, 1-2wks)
- Peptide mapping (2-4wks)
- N-glycan profiling (1-3wks)
- Sialic Acid content (1-3wks)
- Intact glycoforms (1-2wks)
- ADC/DAR analysis (1-3wks)
- Glycation (1-2wks)
- PTMs (1-3wks)
- Size variants By MALS (1-2wks)

Characterizations by Fluorescence

- N-glycan profiling (1-3wks)
- Sialic Acid content (1-3wks)
- Free thiols (1-2wks)

Characterization by DLS/Uncle

- Tm, Tagg, Size, PDI (1-3wks)
  - Monomers
  - Aggregates
  - Oligomers
  - VLPs

Developability Studies (1-2 months)

- Charge variants
  - Oxidation
  - Aggregation
  - Fragmentation
  - Deamidation
- Intact MW
- HIC
- DLS (polydispersity)

Characterization by Multimode Plate Readers

- ELISAs
- Enzyme Kinetics
- FRET assays
- HCP ELISA

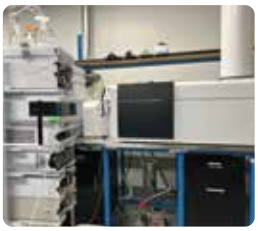
Note: Timeline is approximate and depends on the availability of reagents

Major Medium-High throughput

Instrumentations:

UV-Vis / SCIEX PA 800 Plus/ LC-MS-MS/ SEC MALS, UNCLE and size exclusion chromatography (SEC), SPR, BLI, Multimode plate readers, ELISA (14 colors)

SpectraMax


Agilent Q-TOF


Octet


Nexen-MCS


PA 800Plus

Let's begin the conversation

E: bd@aragen.com
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