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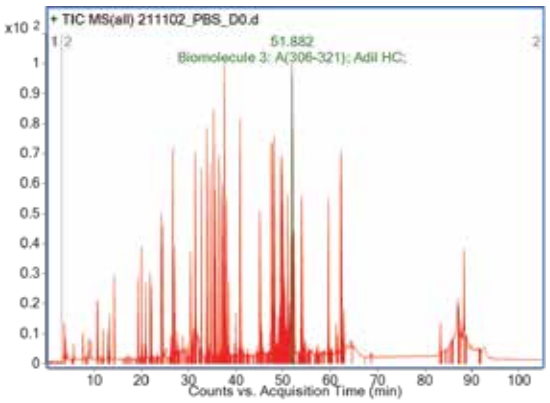
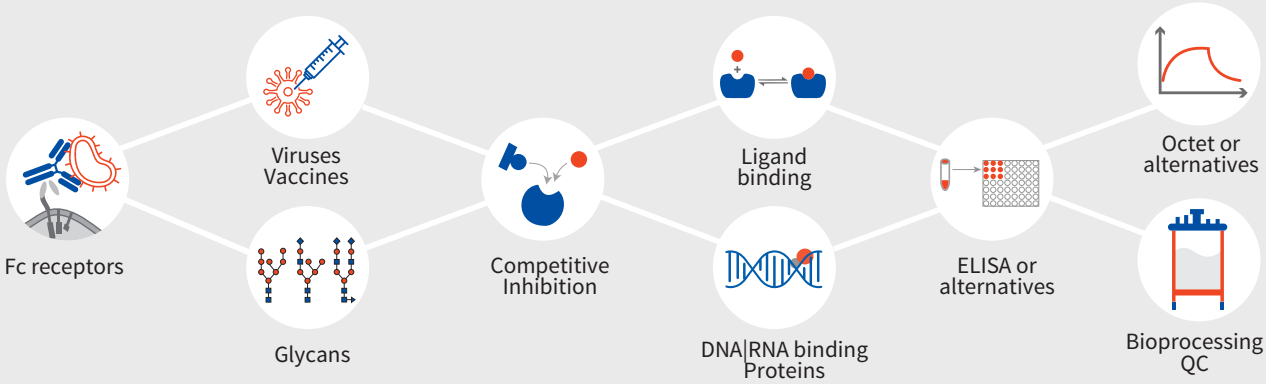
Comprehensive Characterization of Biologics



Biophysical characterization of biologics is critical in the development of biopharmaceuticals such as innovator biologics and biosimilars. Many aspects of biologic drug function, activity, and stability are affected by the physical and biological behavior of proteins. Biophysical analytical techniques, for example, can aid in monitoring or confirming conformational integrity, the nature of the protein's folded state, and how peptides interact to form complex physical structures. Consideration of specific interactions between drug substance and excipients that might potentially alter protein structure and product stability, is critical during formulation development, stability studies, and comparability. Protein degradation and aggregation can also be studied using biophysical techniques.

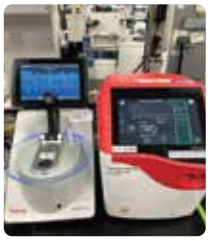
Comprehensive Biologics Characterization



Aragen has established an advanced state-of-the-art, fully equipped analytical laboratory with highly qualified analytical scientists to perform a comprehensive characterization of biologics. The Analytical lab is equipped with state-of-the-art equipment like Octet/BLI, Biacore/SPR, UV-Vis, SCIEX/PA800 Plus, LC-MS/Q-ToF, Wyatt/MALS, UNCLE/SLS/DLS, and SpectraMax multimode plate readers to perform high-throughput analytics. We have the capabilities to characterize the biologics from clients and those produced at Aragen. All biologics analyzed undergo stringent QC checks before shipping to the client.


Biocore 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

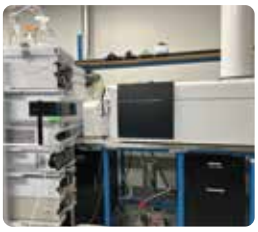
Note: Timeline is approximate and depends on the availability of reagents

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

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