AVID BIOSERVICES

Where collaboration, quality, and reliability meet.

From concept to patients, let us personally take you there.

Our analytical team offers extensive experience in transferring, developing, qualifying, and validating client assays. We tailor our methods to your particular processes and initiate development work at any stage, depending on your needs. Our analytical team works with you to design an analytical program that will adequately characterize your product to meet phase-appropriate regulatory guidelines, from early-phase to commercial.

Capabilities Overview

- Client custom analytical methods development [SEC, IEX, CE SDS, icIEF, etc.]
- Functional assays [bioassay, antigen binding]
- Protein characterization [carbohydrate, peptide mapping, deamidation and oxidation analyses, etc.]
- Validated residual impurity platform assays [HCP ELISA, Protein A ELISA, DNA by qPCR]

Common Assays for Your Biologic Production

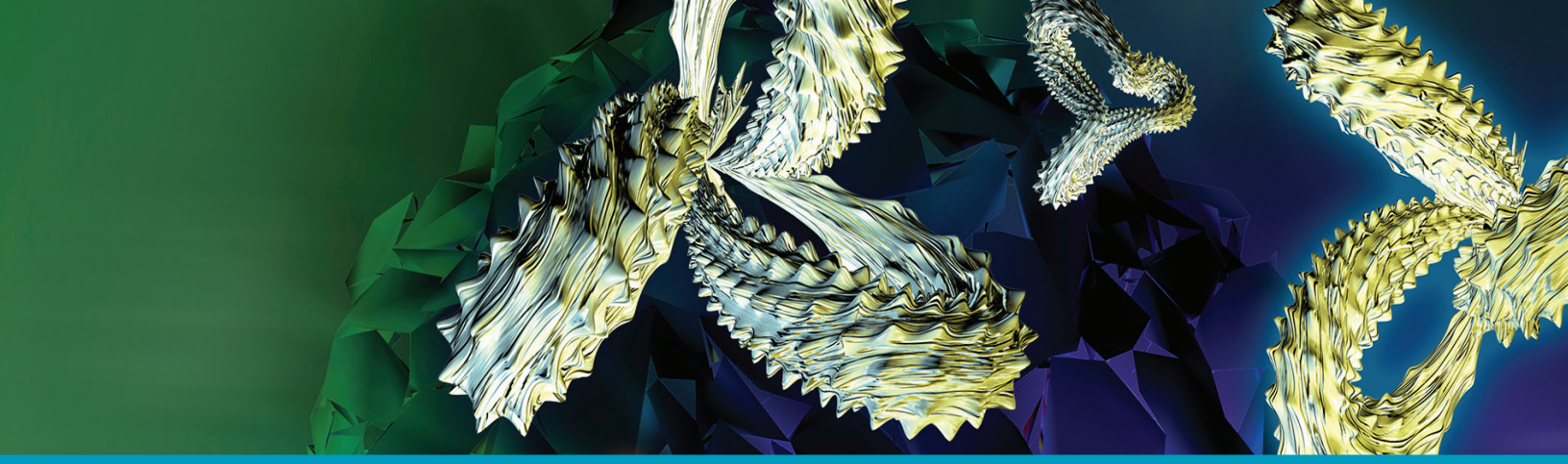
PURITY ASSAYS
- Ion exchange chromatography
- Size exclusion chromatography
- Capillary electrophoresis

IMPURITY ASSAYS
- Residual ELISA (HCP, Protein A, Insulin, etc.)
- Residual DNA by qPCR

IDENTITY ASSAYS
- Peptide map
- Capillary isoelectric focusing

POTENCY & BINDING ASSAYS
- Cell based potency
- Antigen binding ELISA

CHARACTERIZAION ASSAYS
- Reverse-phase and hydrophilic interaction chromatography
  - Sialic acid, glycan and monosaccharide analysis
  - Deamidation and oxidation analysis



High Throughput Analytical

The Avid Analytical Development team can support high throughput screening by leveraging state of the art liquid handling and analytical technologies.

Liquid Handling

- Plate reformatting, serial dilutions, plate replication

High Throughput Instrumentation

- Sartorius Octet HTX
  – Support for HT titer, residual protein A, and residual HCP
- ProteinSimple Maurice
  – High throughput CE-SDS and icIEF
- Waters Acquity UPLCs to support purity and quality assays

Why Avid?

- Experience to troubleshoot challenges throughout the development process, ultimately providing you with a robust and reproducible method
- Customizable analytical development
- Speed to analytical program initiation
- Near real time updates on development status
- Flexibility and access to SMEs

Uncompromising Quality Control

Verifying process and product excellence through science and compliance.

QC Capabilities

- In process testing to support ongoing manufacturing campaigns
- Lot release testing of bulk drug substance to ensure product quality
- Generation of summary of testing and certificates of analysis
- Full support of all process related activities starting with raw material inspection and release through drug substance lot release and stability

Stability

- Full suite of capabilities including stability study design, protocol generation, and time point management
- ICH recommended conditions in validated on-site storage devices
- Ability to provide summary and final reports, including data trending per ICH Q1E

Flexible Paths from Analytical Development to Quality Control

- Transfer of existing validated analytical methods using equivalence models avoiding unnecessary re-validation experiments
- Phase appropriate assay qualification and validation that is custom tailored to your product and process

Process Characterization and Validation Support

- Comprehensive testing solution for process characterization and validation campaigns
- Statistical analysis of all data generated to identify critical quality attributes

We pride ourselves on the personal commitment our team offers, ensuring your project success.

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