

## Analytical Testing for Advanced Biotherapeutics

We support developers of recombinant proteins, antibodies, peptides, nucleic acids, and complex modalities with fast, high-confidence analytical data.

### Mass Spectrometry



- Sequence confirmation
- Post-translational modification (PTM) identification & quantitation
- Modification ratios (e.g., conjugation, engineered variants)



### High-Concentration & Biophysical Testing

- Analytical ultracentrifugation (AUC) for aggregation, self-association, and high-viscosity behavior
- AUC for % ternary complex formation
- Support for bsAbs, fusion proteins, nanobodies, and multi-chain complexes, and proximity inducing proteins



### Chromatography Solutions

- SEC, HILIC, IEC, RP, CE, LCMS
- Aggregate/fragment profiling
- Drug to antibody ratio (DAR) and molecular heterogeneity analysis



### Stability & Developability

- Accelerated + real-time stability
- Light, oxidation, freeze/thaw stress
- Tracking PTM evolution over time



### cGMP Compliant | 21 CFR Part 11 | FDA/EMA Ready

#### Method Development, Qualification, Validation



Biologics manufacturing requires robust analytical methods. We create, implement, and clearly communicate these methods to our partners, providing comprehensive documentation and ongoing support.

#### GMP Release and Stability Testing



Today's research, tomorrow's therapy. BioAnalysis develops robust analytical methods for your research needs. When the time comes, we seamlessly transition to cGMP-compliant testing for regulatory submission and release testing.

# About BioAnalysis

800+

Projects  
Completed (since 2021)

95%

On-Time  
Delivery (2024)

70+

Peer-Reviewed  
Publications

7,000+

Samples  
Analyzed

## Comprehensive Testing

- Bespoke methods
- Cell lysate to commercial product
- Regular meetings with analysts
- Exceeding expectations

## Quality Control

- Host cell protein (HCP) analysis
- Impurity profiling
- Critical quality attributes
- cGMP-compliant testing

## Gene Therapy Expertise

- Viral capsid quantitation
- AAV VP1:VP2:VP3 ratio analysis
- Capsid protein modifications
- Empty/full capsid

## Method Development

- Custom assay development
- Method qualification/validation
- Regulatory support
- Release Testing

## Why Choose BioAnalysis?

- **Scientific Excellence:** Our team delivers rigorous methods and clear results.
- **Client Partnership:** We work as an extension of your team, providing collaborative solutions tailored to your unique challenges.
- **Rapid Delivery:** Efficient workflows and optimized processes ensure timely results without compromising scientific rigor.
- **Proven Track Record:** Supporting numerous IND, BLA, and MAA applications with successful FDA/sponsor audits.

## Modalities We Support

- **Antibodies** (mAbs, bsAbs, nanobodies)
- **Conjugates** (ADCs, AOCs, PDCs)
- **Fusion Proteins**
- **PROTACs & Molecular Glues**
- **Peptides**
- **Nucleic Acids** (mRNA, oligos)
- **mRNA-LNPs**
- **Viral Vectors** (AAVs, Adenos, Lenti)

## Breaking Through

Breaking through scientific barriers starts with breakthrough research. Scan the QR code or visit our website to explore how our published expertise delivers proven solutions for clients like you.

View all publications: [bioanalysisllc.com/technical-hub](https://bioanalysisllc.com/technical-hub)



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