



# Cell Line Development Testing Services

Avance Biosciences provides both phenotypic and genotypic identity testing, enabling selection of the best candidates for further development.



Avance Biosciences is a leading CRO providing CGMP/GLP compliant assay development, assay validation, and sample testing services to support biological drug development and manufacturing activities world-wide.



## CGMP/GLP Compliance

The Avance Biosciences team is committed to strict adherence to CGMP and GLP regulations and guidelines enacted by the US, European, Japanese, and other international regulatory agencies.



## Extensive Experience

Our team has extensive knowledge and experience working with scientists, QA/QC professionals, and project managers from over 100 pharmaceutical and biotechnology companies and organizations throughout the world.



## Cutting Edge Science

Avance Biosciences' CGMP/GLP compliant genomic assays make use of the very latest techniques and technologies including droplet digital PCR and next generation sequencing.

**CONTACT US**



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# Cell Line Development Testing Services

## Supporting Drug Development and Manufacturing

CGMP  
GLP

### Biologic Drug Development Support

Cell line characterization is a critical step in the development of a cell bank that produces a biologic drug. The characterization of each cell line allows the best candidates to be screened for further development. Services offered by Avance Biosciences provide you with the support required to optimize your cell line and efficiently manage your drug development process. To ensure the safety of biologics, the FDA and other regulatory agencies require thorough characterization and qualification of the cell lines using validated assays. This characterization includes both phenotypic and genotypic identity testing. Our CGMP/GLP compliant facilities and extensive molecular biology and microbiology capabilities enable us to provide a wide range of compliant assays and testing services that satisfy regulatory requirements.

### Biological Testing Expertise

Avance Biosciences is a leader in genomic assay development, validation, and sample testing focused on supporting the development and manufacturing of biological drugs. We provide advanced and customized testing solutions designed to facilitate the research and development of your therapeutic products. Avance Biosciences offers customized QPCR, ddPCR, Southern blotting and NGS solutions for both genotypic and phenotypic identity testing of your cell line enabling selection of the optimum candidates for further development and ensuring contaminant free cell banks. All of our testing services are provided with strict adherence to regulatory requirements.

## Trust Avance Biosciences for your Biological Testing Needs

- ✓ Study directors and managers who are highly experienced in leading CGMP / GLP compliant biological testing projects.
- ✓ Independent quality units for assuring regulatory compliance.
- ✓ Professional testing reports which can be readily used in your regulatory submissions.
- ✓ Transparent and routine updates on project progress.
- ✓ Controlled laboratory environments during sample processing to prevent cross-contamination.
- ✓ Rigorous sample management and tracking to ensure chain of custody.
- ✓ Fast turnaround time for product release testing to ensure no delays to the clinic.
- ✓ Over 20 years experience supporting our clients.



## Genotypic Identity Testing

cDNA sequencing data is central to genotypic identity testing. This step confirms the RNA stability of your mammalian or insect cell line.



## Copy Number Variation Analysis

Copy number determination by qPCR provides gene dosage and an indication of productivity whether the copy number is plasmid based or an integrated construct.



## Structural Analysis by Southern Blot

Southern blotting confirms that the correct structure is present in the construct of interest and helps to confirm DNA identity, size, and abundance.



## Rare Mutation Analysis by Digital PCR

Droplet partitioning allows the dPCR method to effectively increase any rare target abundance; each short area of DNA is amplified including the rare mutations.



## Next-Gen Gene Integration Study

Avance Biosciences is now offering two NGS approaches in addition to traditional Southern blot analysis to analyze the transgene insertion sites to satisfy FDA's requirements of characterizing cell line genetic stability.



## Next-Gen Adventitious Agents Testing

Next generation sequencing is quickly gaining regulatory agencies' acceptance as a sensitive and un-biased detection method for adventitious agents.



## Next-Gen Difficult Plasmid Sequencing

Next generation sequencing uses short read lengths and high data volumes which allows repeats and high GC regions to be more easily sequenced than with Sanger sequencing.



## Next-Gen Mutation Analysis

Avance has designed several amplicon sequencing assays to help the client confirm whether mutations exist in their prepared cell lines. Two-step limited cycle PCR is followed by paired-end next-gen sequencing.



## ABOUT US

Our leading scientists have designed and completed hundreds of studies under CGMP/GLP regulations for the FDA, EPA, as well as European and Japanese regulatory agencies. This team has extensive knowledge and experience working with scientists, QA/QC professionals and project managers from over 100 pharmaceutical and biotechnology companies and organizations throughout the world.

Your Trusted  
CGMP/GLP Compliant  
Biological Testing Partner



### Biologic Drug Development Support

Avance Biosciences provides custom CGMP/GLP compliant testing solutions to evaluate the identity, purity and genetic stability of biologics in support of drug research, preclinical safety studies, clinical trials and CGMP manufacturing.



### Assay Development & Validation

With its breadth of service platforms and experienced scientific team, Avance Biosciences offers a broad range of custom assay development services to support all phases of drug development.



### Molecular Biology & Microbiology Testing

Avance Biosciences offers clients worldwide, a variety of molecular biology and microbiology services based on state-of-the-art technology platforms and techniques.



# Science, Compliance, Service



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