AVANCE BIOSCIENCES

Assays To Support Your Biopharmaceutical Drug Development & Manufacturing

Cell Bank Characterization

Custom genomic services to test the identity, purity, and genetic stability of the cell banks

Regulatory agencies require cell bank manufacturers to ensure continued stability and safety of cell lines producing products for human use. Avance Biosciences™ offers comprehensive services for integrated and non-integrated cell lines at all stages of production. The team at Avance Biosciences™, with more than two decades of experience, provides the high quality cell bank characterization services that you need.

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 Bank Characterization

Supporting Bevelopment & Manufacturing of Biotherapeutic Products

Cell Bank Testing Requirements

Characterization of cell banks used for development and manufacturing of therapeutic products is required by regulatory agencies world-wide.

Avance Biosciences™ follows the current FDA and ICH guidelines regarding services provided for cell bank characterization. These guidelines provide references for safety, identity, quality, purity, stability, and strength/potency.

FDA cGMP/GLP 21 Code of Federal Regulations Parts 210/211 and 58. ICH guidance document Q2(R1).

Why Choose Us?

Our success depends on your success; therefore, we do our best to provide reliable, timely, and accurate project completions.

- ✓ Our cell services are validated per ICH guidelines
- ✓ Our staff is experienced in offering GMP, GLP and EPA level genomic services
- ✓ Our professional Project Reports are designed as free-standing additions to regulatory submissions
- ✓ Our competitive and stable pricing is a ideal balance between quality and price
- ✓ Our customers' requirements are at the core of our business
- ✓ Our business was founded to support your needs and we continually adapt our offerings to meet our customers' changing needs.

Sequencing of Expression Construct

High quality, Sanger sequencing is performed using the ABI 3730 XL DNA Analyzer platform and BigDye v3.1 chemistry. We perform DNA or RNA extraction and QC of your samples, as needed. We perform two-fold per strand GMP/GLP custom sequencing of all complexities for your gene identity and stability testing. Fast turn-around service is available, when needed.

Structure Analysis by Southern Blot

The genomic DNA structure of a cell bank is confirmed by Southern Blot. Southern blots determine that your construct is stable and unchanged in abundance, and that no clonal rearrangement has occurred.

Transcript Analysis by Northern Blot

Northern blots confirm the particular gene expression rates of a cell bank by detecting mRNA levels of the gene of interest. Northern blots can also detect the size of RNA and observe any alternative splicing products. The expression of mRNA in a cell bank can be affected by growth conditions, contaminants, and other problems.

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Cell Bank Characterization

Copy Number Analysis by qPCR

The ABI 7900HT Sequence Detection System is used to measure both target and host DNA in your cell line by qPCR. For your expressing construct that is integrated into the host cell genome, Avance Biosciences provides all necessary expertise from assay design to consultation regarding the use of a host gene normalizer.

Restriction Fragment Analysis of Plasmid

Restriction Enzyme Analysis is used to evaluate the genetic stability of a plasmid construct by evaluating the restriction profile in comparison to a reference project or to the restriction pattern determined from the sequence of your plasmid.

Marker Retention Testing

Marker retention or plasmid loss follows a selectable marker in the cell line plasmid such as antibiotic resistance. By culturing aliquots of cells on media with and without the selectable marker, the percentage of cells in the bacterial strain that have lost the marker or plasmid may be determined.

Microbial Cell Viability Assay

Services are performed to determine the percent of live cells in a cell bank sample.

Bacteriophage Testing (Lytic and Prophage)

This service tests for the presence of lytic phage contaminants in your cell line. Mitomycin C induces active phage from the prophage stage which is difficult to detect. Your cell bank will be tested with and without Mitomycin C to determine the presence of prophage. If phage are present the titer is determined.

Bacterial and Fungal Impurity Testing

Evaluating the purity of microbial cell lines from bacterial and fungal contaminants in both aerobic and anaerobic environments.

Bacterial ID by API 20E

The API-20E test strip (from bioMerieux, Inc.) is used to identify enteric gram negative rods. A bacterial suspension rehydrates each of 20 wells which contain various biochemical identifiers that are diagnostic for Enterobacteriaceae family; an oxidase test is also performed to determine if the sample is Gram positive or Gram negative.

Gram Staining

A sample of a bacterial cell line is stained with trypan blue which enters dead cells only; the percentage of viable cells is calculated verses the total number of cells observed.

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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