



**Minaris**  
Advanced Testing

# Cell Banking

Manufacturing • Testing • Characterization • Release

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[minaris.com](https://minaris.com)

# Accelerating Time to Market

Minaris Advanced Testing offers comprehensive, GMP-compliant biologics testing services to clients across the entire life sciences industry. With one of the most advanced biologics-focused QC facilities in the world and a deeply experienced scientific team, Minaris delivers the speed, reliability, and regulatory rigor required for today's complex biologics pipelines.

Our services and solutions accelerate time to market and support patients around the world.



## Integrated Manufacturing and Testing

Co-Located in One Organization

Regulatory agencies worldwide require a continuous and well-controlled supply of the specific cell lineage utilized in your manufacturing process.

Our team of experienced cell culture and bioanalytical specialists will manufacture your bank and provide the test results and documentation required to release it under industry recognized quality assurance standards.

Our team can manufacture your R&D, Master, Working, and End of Production Cell Banks and perform the necessary testing to prepare the required regulatory documentation.

We will collaborate with you on your process and work with you to optimize the final product in the shortest timeline possible.

[Contact us](#) for a quote today!

# Robust Track Record



## 20+ Years of cGMP Cell Banking Experience

Our team has manufactured and released cell banks across a wide variety of cell types for products in all phases of production from pre-IND to commercial.



## Integrated Testing and Characterization

We will help you demonstrate and document recovery viability, growth, biosafety and genetic characterization and provide a QA-approved Certificate of Analysis (COA).



## From Research Grade to Commercial

Whether you need research, working, master or end of production cell banks, we can provide the guidance, manufacturing and testing support required to meet regulatory guidelines.



## Ability to Right-Size Production

Our team can work with you to verify and optimize your cell growth and expansion plan and scale to produce anywhere from 10-1,200 vials.

# Why Choose Us?



## Integrated Testing & Characterization

Our team leverages our co-located testing and characterization services to confidently release your bank including cell line identification, viability and purity.

Please get in touch for a full list of all the assays and testing services available with associated sampling requirements, turnaround times and pricing.



## Proven Templated Approaches

You will have the opportunity to utilize our batch record templates for your cell bank.

By leveraging these proven templates, you can shave weeks off your production timeline and capitalize on GMP ready documentation that has already been resulted in successful production.

## Cell Line Experience

Our team has experience with a wide array of cell lines .

### Mammalian

- Embryonic Retina (PER-C6)
- Spleen
- Kidney (MRC-5)
- Neuroblastoma cells
- Embryonic Kidney (HEK 293)
- Umbilical cord

### Murine

- Hybridoma
- Hybridoma Sp2/0
- Myeloma (NSO)

### Monkey

- Africa Green Monkey (VERO)
- Rhesus Monkey (LLC MK2)

### Insect

- Drosophila S2
- Fall armyworm Sf9

### Hamster

- Ovary (CHO)

### Canine

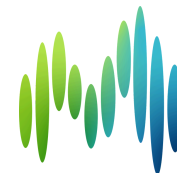
- Kidney (MDCK)

### Chicken

- Embryo



# Cell Line Characterization



The following table is our standard testing package for cell line characterization. All testing is executed by Minaris Advanced Testing in full cGMP compliance to inform your downstream needs as quickly as possible.

Category	Assay Type
<b>Identity</b>	Cell morphology
	Non-Human Cell Line ID by NGS
	Human Cell Line ID by STR
<b>Genetic Stability</b>	Gene of interest (GOI) sequencing
	Gene of interest (GOI) copy number
<b>Safety - General</b>	Sterility
	Mycoplasma
	Mycobacterium
	Detection of reverse transcriptase by PBRT
	Transmission electron microscopy (TEM)
	In vitro virus assay
	In vivo virus assay
<b>Safety - Virus Specific</b>	9CFR for bovine, porcine, or equine viruses
	Antibody production: MAP/HAP/RAP
	Species specific viruses by PCR (e.g. MMV, calicivirus, bovine, porcine, human virus panel, simian virus panel)
	Replication competent viruses screening assays (e.g. RCR, RCL, rcAAV, RCA)
	Retroviruses (e.g. PG4 S+L-, co-cult with Mus dunni, extended XC)

In addition to providing cell line characterization, Minaris Advanced Testing can support the full cGMP manufacturing and release of your working and master cell banks.

# Our Capabilities

We have proven and robust quality systems which have been audited by numerous clients and the US FDA. Your cell bank(s) will be produced and tested under a single work order, saving you time and effort in contracting.

A dedicated project manager will coordinate all manufacturing and testing activities, saving you time and reducing risks through streamlined and direct communication.

## Cell Culture Platforms

- T-Flasks
- Shaker Flasks
- Spinner Flasks
- Roller Bottles
- Cell Factories
- Hyperstacks



## Cell Expansion & Harvest

- Capacity to manufacture 10-1,200 vials
- Campaign production approach
- Stringent raw materials release program
- Seed stock contamination acceptance screening
- Validated change-over and cleaning procedures

## Batch Record Development

- Consultation to determine needs
- Clarify raw materials and process requirements
- Documentation of cell line history, growth profile and safety & characterization data





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