Biosafety Testing. Simplified.

Minaris Advanced Testing

Flyer

Minaris Advanced Testing is a leading global provider of biosafety testing for mAbs, recombinant proteins, viral vaccines, and cell and gene therapies. With more than 40 years of experience and a strong regulatory track record, our U.S.-owned and operated labs deliver coordinated molecular, microbiological, viral safety, and viral clearance services through a streamlined, client-focused approach. We simplify the testing journey by combining scientific excellence, deep expertise, reliability, and responsiveness to help you accelerate delivery of your therapeutics to patients worldwide.

- Comprehensive services and streamlined processes make outsourcing testing easier
- Fast, industry-leading turnaround times
- 500+ filings supported
- 25+ commercial molecules tested
- Cell & gene therapy testing standalone or integrated with CDMO services

OUR TESTING SERVICES

Accelerating Biologics and Advanced Therapies with Streamlined GMP Biosafety and Characterization Testing

Analytical Development / Assay Transfer

- Assay design, optimization and validation paired with regulatory Strategy & QA to align with submission requirements
- Proven expertise transferring and qualifying a range of methods, including potency, identity and purity assays and platform specific methods

Cell Banking and Characterization

- 20+ years of GMP cell bank manufacturing experience
- RCB, WCB, MCB from research grade to commercial

Lot Release

- Phase-appropriate testing backed by qualified and validated methods
- Standard and expedited packages with customization available

Potency

- Custom-developed or transferred in to support release, comparability and stability programs
- Option to complete in parallel with product development

Stability

- Protocol development and execution tailored to your product and regulatory strategy
- ICH Q1-compliant

Viral Clearance

- Deep experience tailored to your process, product class and development phase
- Aligned with ICH Q5A(R2), WHO guidelines and FDA/EMA expectations

Built for Speed, Compliance and Scale.

Our 140,000 ft² facility in Philadelphia, PA is dedicated to biologics and cell and gene therapy testing, featuring more than 20 GMP-compliant biosafety level 2 and 2+ laboratories.

Since tripling its capacity in 2021, the site has built extensive experience managing health authority inspections, ISO and QP requirements, and an average of over 60 client audits each year.

Analytical
(Compendial methods, ELISA, SDS-PAGE, HPLC, UPLC, etc.)

Cell Biology
(RCB, MCB, WCB)

Virology
(In Vitro, RCL, RCA, rcAAV, TEM, etc.)

Cell Potency
(Proliferation, cytotoxicity, flow cytometry, cytokine production)

Molecular Biology
(qPCR, ddPCR, next generation sequencing, etc.)

Who we serve

Biologics and Biosimilar Products
mAbs, recombinant proteins

Viral Vector Producers
AAV, LVV, AdV, RVV

Vaccine Programs
Viral and protein-base

Cell and Gene Therapy Developers
Autologous, Allogeneic, Gene edited, Non-edited

Minaris Advanced Testing

CONTACT US

Get in Touch With Our Team Today

minaris.com/contact

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