Viral Clearance Testing for Biologics, Vaccines & AAV Therapies

Minaris Advanced Testing

Flyer

Minaris Advanced Testing is a global leader in viral clearance studies supporting monoclonal antibodies, vaccines, and AAV-based therapies. Backed by 40+ years of viral safety expertise and zero regulatory rejections, our U.S.-owned and operated laboratories deliver scientifically defensible spiking studies supported by compliant, audit-ready documentation.

We provide flexible execution models—client-run studies in dedicated viral suites, full Minaris execution, or hybrid collaboration—delivering the technical oversight, speed, and regulatory involvement required. Through advanced virus production, precise quantification methods, and responsive GLP documentation, Minaris accelerates IND and BLA submissions with confidence. confidence.

Why Viral Clearance Matters

- Protect patients by preventing adventitious viral contamination
- Required by global regulatory agencies (ICH Q5A, FDA, EMA)
- Demonstrates validated viral inactivation and removal across manufacturing steps

Minaris at a Glance

40+
Years of viral safety experience

3,000+
Viral clearance studies completed with zero rejections

5
Private viral clearance suites in our Philadelphia facility

100%
Client-dedicated offices newly renovated for your comfort

24/7
Remote monitoring, on-site IT support, and flexible access

Full
IND/BLA submission support for mAbs, proteins, vaccines, and gene therapy

Minaris Viral Clearance Differentiators

Ultra-Purified High-Titer Virus Spikes Manufactured In-House

- Enhanced virus quality enables improved detection sensitivity and stronger LRV outcomes
- Purified virus spikes show minimal or no impact on process step performance

Large-Volume Testing & Plaque Assays

- Increases LRV accumulation and deepens purification evaluation
- Higher LRV per step = fewer study steps + faster regulatory advancement

Advanced Viral Clearance Database

- Historical insight informs smarter study design and predictive clearance performance

Scientist-to-Scientist Collaboration

- Expert guidance from study planning through regulatory filing support

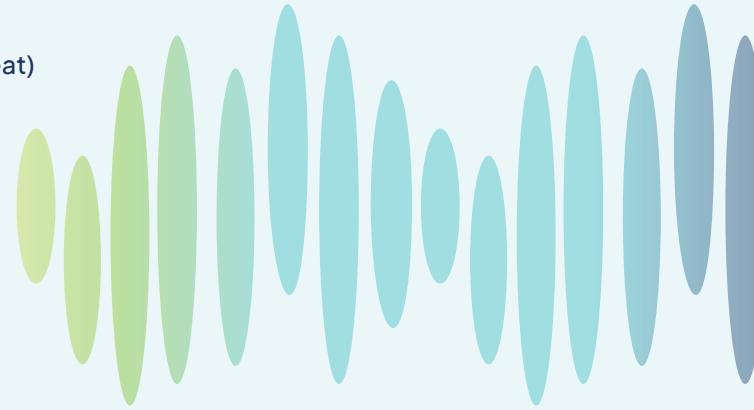
Process Design & Scientific Rigor

→ Evaluates both inactivation (low-pH, solvent/detergent, heat) and removal methods (chromatography, nanofiltration)

→ Uses enveloped and non-enveloped model viruses in scaled-down manufacturing conditions

→ Full GLP documentation includes:

- Cytotoxicity and spike recovery analyses
- Scaled-down model justification
- Log reduction calculations
- Technical transfer, QA review, and regulatory-ready reporting



Speed to Submission

Minaris Advanced Testing

CONTACT US

Get in Touch With Our Team Today

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