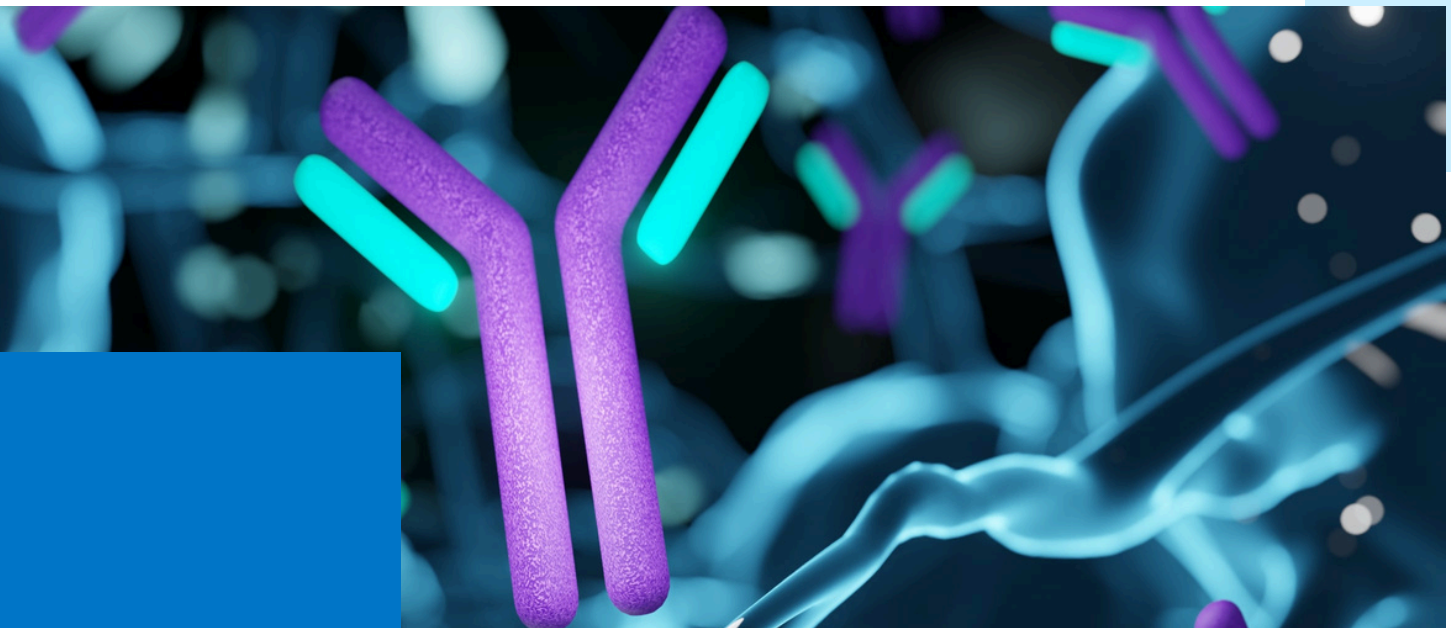




mAb / Recombinant Protein

Lot Release Package

As of October 2025



mAb/Recombinant Protein Lot Release

Below is our standard testing package for mAb and Recombinant Protein lot release. During our 20 plus years of bioanalytical testing experience, Minaris Advanced Testing has successfully served hundreds of clients including over 50 commercial lot release programs.

We have provided consistent and reliable testing for biological products and understand the criticality of timely lot release testing. All testing is executed by Advanced Testing in full GMP compliance to inform your downstream needs as quickly as possible.

Category	Assay Type
Adventitious Agents	Sterility
	Bioburden
	Mycoplasma
	In vitro adventitious virus
	Endotoxin
	9CFR for bovine or porcine or equine viruses
	Mycobacteria
	Detection of reverse transcriptase by PBRT
	PCRs for specific viruses
	Transmission electron microscopy (TEM)
Residuals	Residual host cell protein and DNA (including sizing)
	Process-related residuals (e.g. Protein A, benzonase)
General Characteristics	Color/appearance/sub-visible particles
	pH/residual moisture/aggregates
	Osmolality/extractable volume

In addition to providing lot release testing, Minaris Advanced Testing can support the full lifecycle of your product including Cell Banking with lot release and characterization testing as well as Viral Clearance studies.

ABOUT US

Enabling the Future of Medicine

With more than 40 years of bioanalytical testing experience, Minaris Advanced Testing has supported 140+ Biologics and Advanced Therapy clients and understands the criticality of timely lot release testing.

We have provided consistent and reliable testing for biologics including more than 50 commercial lot release programs.

Dedicated, Modern, Testing Facility

Our expansive campus at the Navy Yard in Philadelphia, PA boasts a new 140,000 square foot facility which was designed for purpose and is completely dedicated to our testing business.

The facility, called Rouse 400 or R400, has proven regulatory success with the EMA, TGA, Health Canada and FDA.

Visit www.minaris.com to learn more or request a quote.



GET IN TOUCH WITH EXPERTS

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THANK YOU!

Our extensive team of customer-focused project managers and scientific experts look forward to supporting your lot release and serving your target patient population.

