Investing in the NGS Rapid Analytics that Cell Therapy Needs.

From characterization today to rapid analytics tomorrow.

The science of cell and gene therapy has advanced faster than the economics of manufacturing it. At ElevateBio, we are closing that gap. That means automation, facility design, and now a dedicated Next-Generation Sequencing (NGS) program built directly into our manufacturing operation.

Manufacturing has gotten faster. Release testing hasn't.

That's what our investment in NGS is built to resolve.

A Testing Panel Designed for a Different Era

Releasing a cell therapy batch today means clearing a testing panel that wasn't built for living, time-sensitive products. The compendial sterility test requires 14 days of incubation. Mycoplasma testing can take up to 28 days. Adventitious agent testing is often outsourced entirely, at significant cost and delay.

In small autologous runs, the sample demand from just these three assays can exhaust available volume. And they represent just part of a release panel that today requires multiple instruments and significant hands-on analyst time per batch.

These methods were developed for pharmaceutical products that can wait. Autologous cell therapies cannot.

The Current Release Testing Reality

28*
days — compendial mycoplasma testing requirement

5–14
days — sterility testing under standard methods

~12 mL
drug product consumed per testing cycle

**USP <63> compendial standard. Alternative rapid methods exist but require extensive validation.*

A Different Kind of NGS Lab

Built Into the Manufacturing Organization, Not Alongside It

Most programs that need sequencing data face an uncomfortable choice: send samples to an external vendor and wait weeks or build internal capability from scratch. ElevateBio is a third option.

Our NGS core is integrated directly with manufacturing and process development. The scientists running sequences and the teams making process decisions are the same organization. That connection is uncommon in CDMO settings. Few partners can offer it.

Speed is another advantage. Our automated bioinformatics pipelines return results in days, not weeks. Faster data means faster decisions, and in autologous cell therapy, every day between manufacture and infusion counts.

The lab supports a full range of sequencing applications.

Sequencing Types

- Amplicon
- Whole Genome & Whole Exome
- RNA (incl. Single-Cell)
- Complete Plasmid
- Methylation

Applications

- Vector genome characterization
- Insertion site mapping
- CRISPR on/off-target assessment
- Assay design consultation
- Custom panel design

Performance

- Illumina · Oxford Nanopore · 10x Genomics
- Amplicon turnaround time (TAT) < 1 week
- Advanced assays 2–4 weeks faster than industry standard
- Automated bioinformatics pipelines
- Only Twist NGS Pro Lab in New England

Where This Investment Is Going

The NGS lab is the foundation. Rapid analytics is what we're building on top of it.

Safety Testing

In Development

Consolidating Three Tests Into One

ElevateBio's rapid analytics program is focused on a single target: developing and replacing a three-test safety panel with one NGS-based assay. Sterility, mycoplasma, and adventitious agent testing currently require separate samples, separate analysts, and 5 to 14 days. One workflow has the potential to replace all three.

Early data demonstrates detection of five bacterial and fungal species and six viral species, down to 1–10 CFU or viral genome copies per sample. The assay is built to be automation-ready and fully multiplexed. Unlike culture-based methods, sequencing identifies contaminants at the species level in the same run, with no separate investigation required.

Current State vs. Rapid Analytics Target

	Today	Rapid Analytics Target
Number of assays	3	1
Assay duration	5-14 days	4-5 days
Release turnaround time	8 days	6 days
Sample volume	mLs	µLs
COGS (sterility + myco)	Baseline	~65% reduction
Contaminant ID	Separate investigation	Real-time, same assay
Automation potential	Limited	Fully automation-ready

What This Means for Your Program

Faster Release

Target release TAT of 6 days, down from 8. For autologous programs, shorter vein-to-vein time is a clinical outcome, not just an operational one.*

Protect Your Product

From requiring mLs per testing cycle to a target of µLs. For programs where every cell counts, that difference is significant.

Lower Manufacturing Costs

Projected COGS reduction: 65%. One assay, one qualification, one set of reagents.

Deeper Detection

NGS screens for bacterial, fungal, and viral contaminants simultaneously (including organisms that don't culture) with species-level ID in the same assay.

Beyond Safety: The Longer Investment Arc

Rapid analytics begins with safety testing consolidation, but that's not where the vision ends. The full cell therapy release panel runs more than a dozen assays across identity, potency, and purity. NGS is positioned to address more of that panel over time.

The next phase extends NGS to vector copy number, identity testing, and ultimately potency. Sequencing-based methods already show advantages over PCR in each of these areas. ElevateBio is investing ahead of that shift. We believe sequencing will become foundational to how cell therapy products are released, and the partners who get there early will have a meaningful advantage.

Start the Conversation →

Whether you need NGS characterization support today or are thinking about how rapid analytics fits your release strategy, let's talk.

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*Locke FL et al. Impact of vein-to-vein time in patients with R/R LBCL treated with axicabtagene ciloleucel. Blood Advances. 2025;9(11):2663–2676. | † USP <63> compendial standard.