

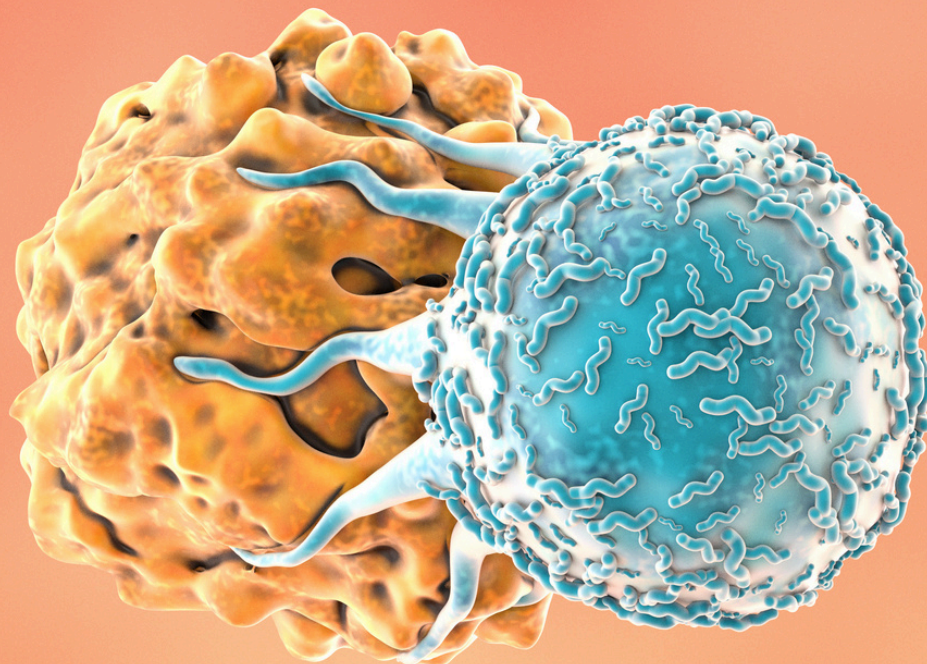


# Cell Therapy

Lot Release Package

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As of October 2025



# Cell Therapy Lot Release

Below is our standard testing package for cell therapy lot release. All testing is executed by Minaris Advanced Testing in full cGMP compliance.

| Category  | Assay Type   |
|---|--|
| <b>Cell Therapy Product Specific</b>              | Cell morphology / cell viability / cell count  |
|   | Vector copy number by PCR  |
|   | Human cell line ID by STR  |
|   | Identity via cell surface markers by flow cytometry  |
|   | % cell population by flow cytometry  |
|   | Potency assay  |
| <b>General Safety</b>                             | Sterility by BacT  |
|   | Mycoplasma by PCR  |
|   | Endotoxin  |
|   | In vitro virus assay *   |
|   | Human viral PCR panel *  |
| <b>Additional Safety Based on Risk Assessment</b> | Species specific viruses by PCR ( <i>e.g. bovine, porcine, human virus panel, simian virus panel</i> ) |
|   | Replication competent viruses screening assays ( <i>e.g. RCR, RCL</i> )                                |
|   | Residual process impurities ( <i>e.g. beads, cytokines</i> )   |
| <b>General Characteristics</b>                    | Color/appearance   |
|   | pH   |
|   | Osmolality   |

In addition to providing cell therapy lot release testing, our team provide full cell line characterization, and cGMP manufacturing and release of your working and master cell banks.

\*Only needed for allogenic products.

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](http://www.minaris.com) to learn more or request a quote.



GET IN TOUCH WITH EXPERTS

# Connect with us



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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.

