

CELL & GENE THERAPY MANUFACTURING SOLUTIONS

IMMUNE CELL THERAPY
REGENERATIVE MEDICINE



biotechne[®]

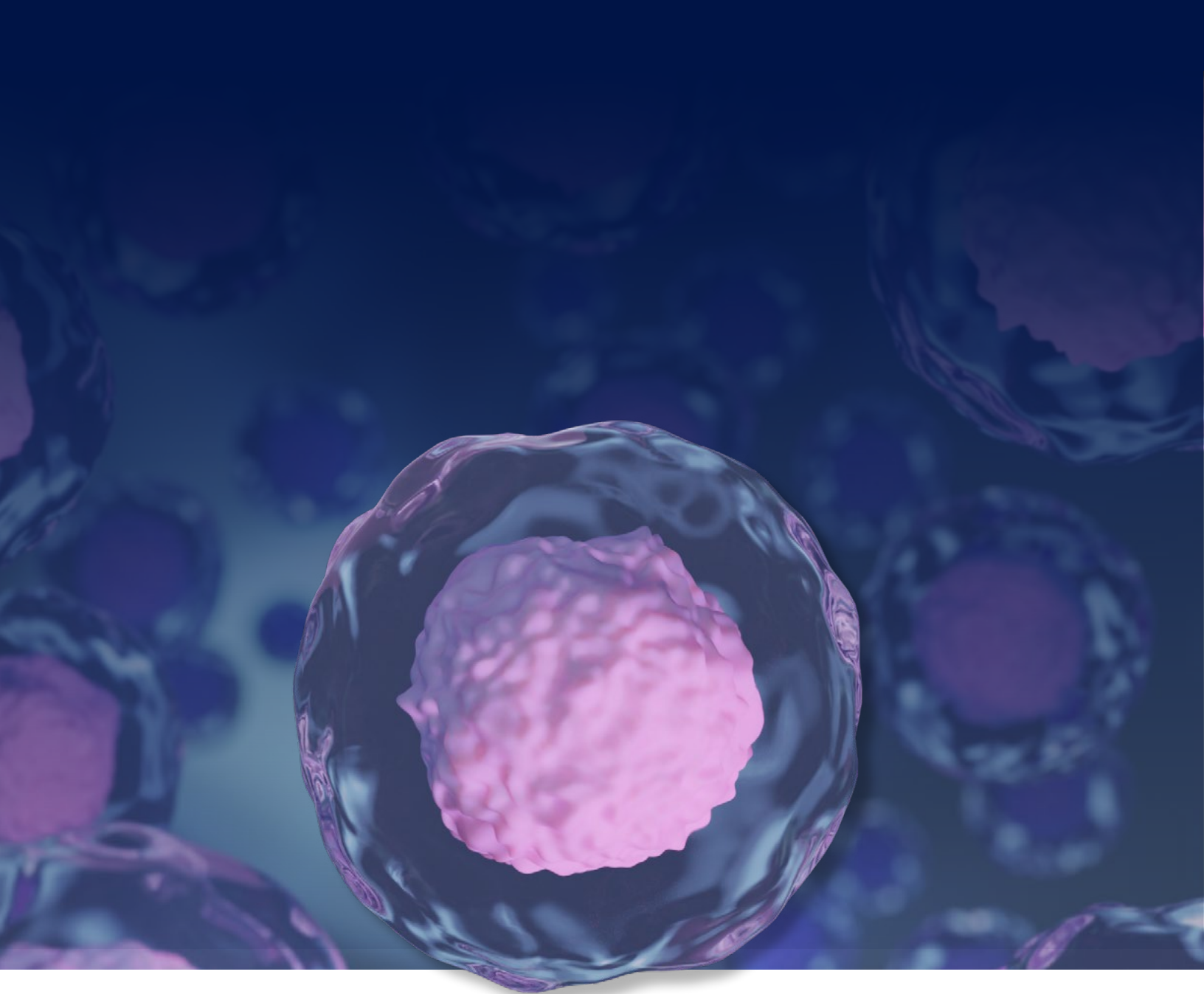


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Revolutionary cell and gene therapies offer exciting promise to treat life threatening diseases. Bio-Techne is in this journey with you. As a full-solution ancillary reagent, services, and instrument provider, we will stand by you, providing flexible and pioneering tools to simplify your workflow at every step of the manufacturing process. From CAR T cells in immune cell therapy to pluripotent stem cells for regenerative medicine, let us help you get your therapy to market.

You can count on Bio-Techne to provide solutions focused on:

- Innovation
- Scalability
- Flexibility and Customization
- Consistency and Reproducibility
- Reducing Manufacturing Risk

TRANSITIONING FROM RESEARCH TO GMP

As you develop new therapies and advance from preclinical studies to clinical manufacturing, we are here to support you. We make the transition as efficient and seamless as possible. Incorporation of GMP or [Ancillary Material-grade](#) raw materials early in your program will simplify your transition. If GMP-grade raw materials are not available, we will work with you to convert RUO materials for manufacturing use.

FITTING THE PRODUCT TO THE PROCESS WITH CUSTOMIZED SERVICES

We will work with you to develop and deliver GMP raw materials and services that meet your unique process requirements. We can provide customized vialing by mass and activity, construct design, formulation, and quality control analysis. If particular GMP products are not available, we can develop them specifically for you. With a dedicated project manager, our expert scientists, quality assurance team, and world-class technical support, we will provide solutions exactly tailored to lower the burden of comparability proof during later stages.



GMP Capabilities

Each of our GMP manufacturing facilities is ISO certified. We ensure quality compliance with a team of quality and regulatory experts. [Learn About Our GMP Capabilities](#)

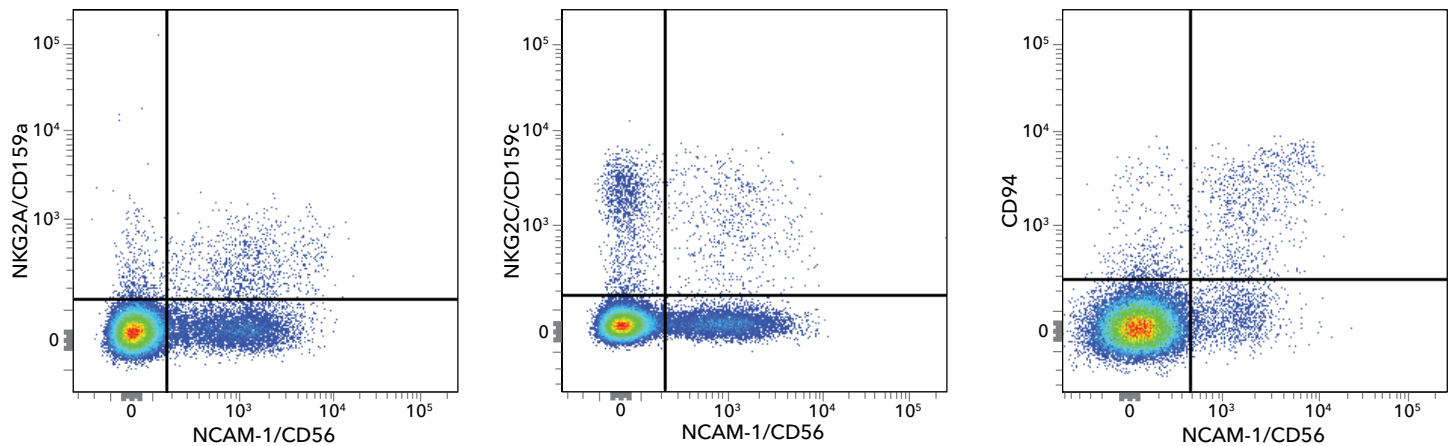
Visit | bio-techne.com/services/custom-cell-and-gene-therapy-services

CHARACTERIZATION OF ISOLATED CELLS

Qualifying a robust starting cell population is essential for **immune cell** and **stem cell** manufacturing processes. The quality of the cells at the beginning of your manufacturing pipeline will directly impact the efficiency of your cell expansion and differentiation protocols.

In addition to our vast portfolio of premium **flow cytometry** and IHC/ICC antibodies, we offer custom antibody services that cover:

- Custom antibody development
- Custom monoclonal antibody panels
- Custom fluorophore conjugations
- Recombinant antibody conversion
- Custom GMP Antibodies

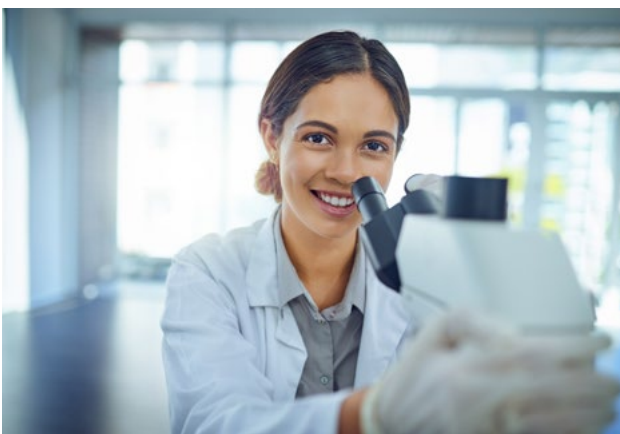


Analysis of distinct **natural killer cell** populations by flow cytometry. The detection of multiple NK cell receptors allows rigorous qualification of starting cell preparations. Human PBMC were stained with conjugates of **NCAM-1/CD56** antibody and either **NKG2A/CD159a** (left), **NKG2C/CD159c** (center), or **CD94** (right).

CUSTOM ANTIBODY SERVICES

Leverage the experience and expertise of our **Custom Antibody Services** for your project. Our consultative, stage-gated approach mitigates process risk, saves time, and eliminates obstacles to advancing your program.

Visit | [bio-techne.com/services/custom-cell-and-gene-therapy-services](https://www.bio-techne.com/services/custom-cell-and-gene-therapy-services)



When your work demands unique reagents or scientific support, turn to the decades of product development legacy behind Bio-Techne's trusted brands. Together with a dedicated project manager, our expert scientists, quality assurance team, and world-class technical support, we will deliver solutions exactly tailored to bring you success faster and more economically.

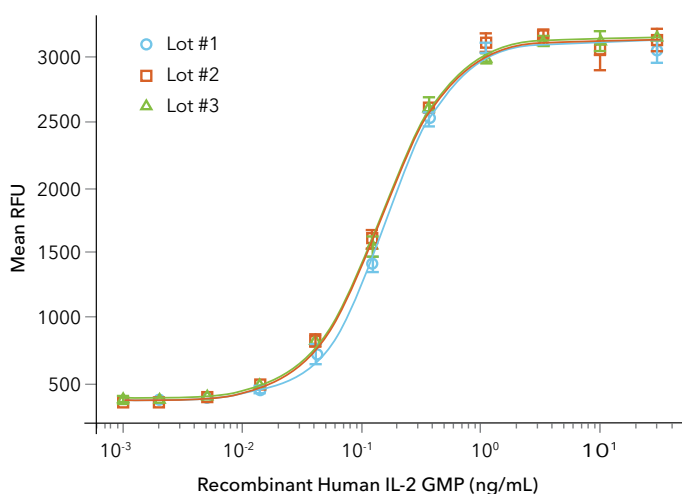
CELL CULTURE

Ensure the most robust cell expansion possible for your cell and gene therapies. We can help you achieve rapid cell proliferation and high viability to quickly generate the large cell numbers you need for therapeutic doses.

GMP CYTOKINES AND GROWTH FACTORS

We test the bioactivity of every production lot in side-by-side comparisons to a master lot to ensure consistency over time and facilitate lot bridging.

- IL-2, -3, -4, -6, -7, -15, -21
- Activin A, FGF basic, Noggin, SCF
- And many more



Visit | bio-techne.com/gmp-proteins

GMP SMALL MOLECULES

We follow relevant sections of ICH Q7 guidelines to ensure consistency, traceability from start to finish, and animal-free production.

- [Y-27632](#) (ROCK inhibitor)
- [SB 431542](#) (TGF- β RI inhibitor)
- [CHIR 99021](#) (GSK-3 inhibitor)
- [XAV 939](#) (Tankyrase inhibitor)

Our Ancillary Material (AM) grade of small molecules provides increased manufacturing control compared to research-grade.

- [DAPT](#) (γ -Secretase inhibitor)
- [WIKI4](#) (Tankyrase inhibitor)
- [RepSox](#) (ALK5 inhibitor)

Visit | bio-techne.com/gmp-small-molecules



GMP ProDots™ Proteins are formulated as pre-aliquoted, dissolvable spheres, packaged in single-use bags for easy welding into closed systems for media preparation.

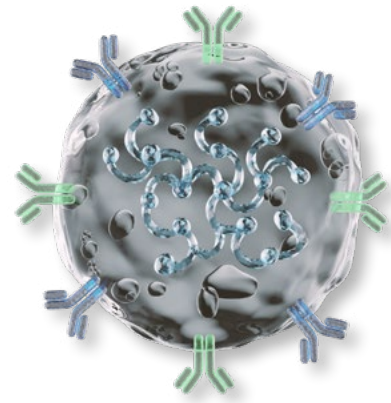
- IL-2, IL-7, IL-15 plus IL-21 coming soon

Bioactivity comparison of three production lots of GMP ProDots IL-2 in a proliferation assay with CTLL-2 cytotoxic T cells.

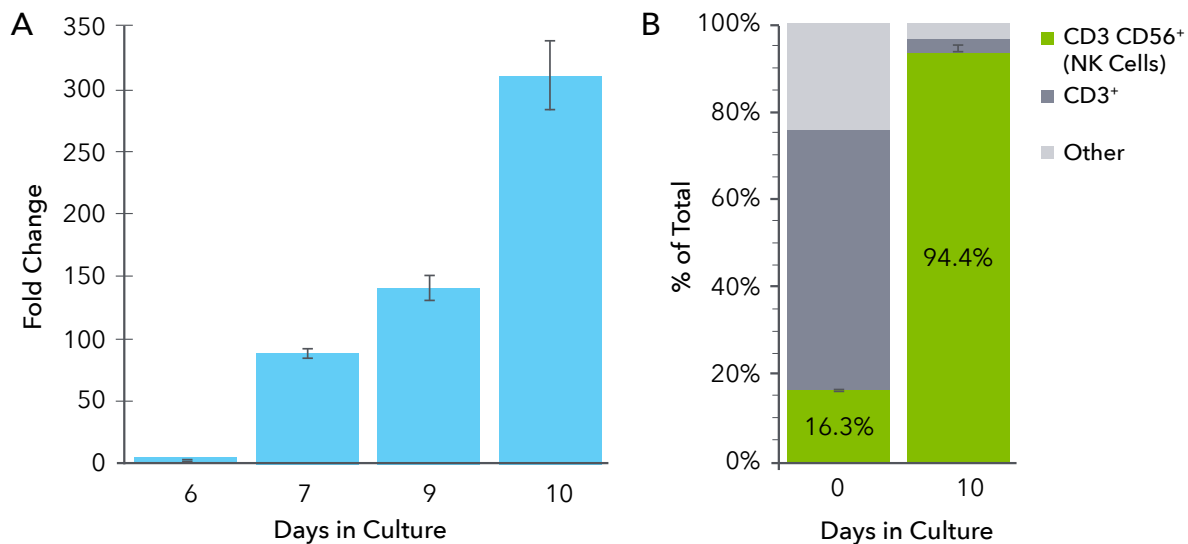
	STANDARD CATALOG	ANCILLARY MATERIAL GRADE	GMP
ISO 9001	✓	✓	✓
QC Testing	✓	✓	✓
Controlled Manufacturing Zone		✓	✓
ISO-7 Cleanroom		✓	✓
Endotoxin/ Bioburden Testing		✓	✓
TSE and BSE Certification		✓	✓
Risk-based Approach to Manufacturing			✓
ICH Q7			✓

GMP CLOUDZ™ CELL ACTIVATION KITS

Cloudz is a unique and customizable cell activation platform based on an alginate hydrogel. Cloudz reagents are conjugated with cell-activating antibodies or ligands and rapidly dissolve with the addition of release buffer.



- Human T Cell Activation Kits, [GMP](#) and [RUO](#) available
- Human Treg Expansion Kit, [GMP](#) and [RUO](#) available
- Human NK Cell Expansion Kit, [RUO](#) available



Human PBMCs were expanded with the [Cloudz Human NK Cell Expansion Kit](#). Following 10 days of culture NK cells showed approximately 300-fold expansion (A) and a purity of 94.4% of CD3-CD56+ cells (B).

Visit | rndsystems.com/products/cloudz-cell-activation-kits

GMP AND XENO-FREE CELL CULTURE MEDIA

Partner with us for the optimum media and supplements for your process. Our expertise covers GMP media production, media formula optimization, and specialty testing assays.

- [StemXVivo™ GMP Mesenchymal Cell Media](#)
- [GMP N-2 MAX Media Supplement](#)
- [ExCellerate™ Human T Cell Expansion Media, Xeno-Free](#)
 - GMP-grade coming soon
- [ExCellerate NK Expansion Media, Xeno-Free](#)
- [ExCellerate B Cell Media, Xeno-Free](#)

Visit | bio-techne.com/services/custom-cell-and-gene-therapy-services

GENE ENGINEERING SERVICES

Let us solve your challenging gene engineering needs so you can focus on groundbreaking research and manufacturing. Our gene engineering services team specializes in complex projects and hard-to-transfect cell lines.

- Cell modification using TcBuster™, our non-viral gene delivery system
- Custom gene editing services to deliver simple and complex engineering solutions in a realistic timeframe
- iPSC engineering services (RUO and GMP capabilities) for regenerative medicine therapies
- GMP process development for your CART-T, TCR, or iPSC therapies
- CDMO services for large scale isolation, cell engineering & activation, final fill & finish



Monitor the identity and purity of your viral vectors with automated, multi-attribute immunoassays. Our iCE Maurice™ and Simple Western™ systems deliver precise and sensitive analysis for vector and viral protein characterization.



CUSTOM SOLUTIONS FOR GENE ENGINEERING

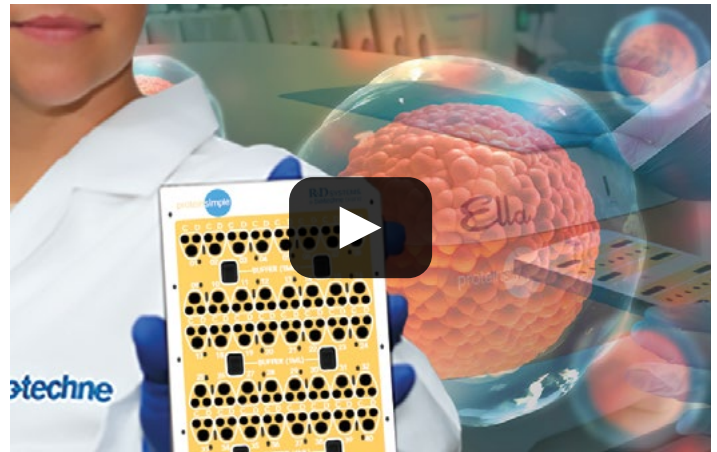
We offer dedicated project management supported by our Custom Services team. Regardless of the project, we can customize all deliverables including the number of cells/vial, validation testing, datasheet preparation, and batch record documentation.

Visit | bio-techne.com/services/gene-engineering-services

PRODUCT RELEASE TESTING

Cell therapies are classified as Advanced Therapy Medicinal Products (ATMPs) and require rigorous phenotypic and purity characterization before final release. Our pioneering technologies allow you to generate reliable and accurate data for release testing to ensure that your cell therapy gets to the clinic as fast and as safely as possible.

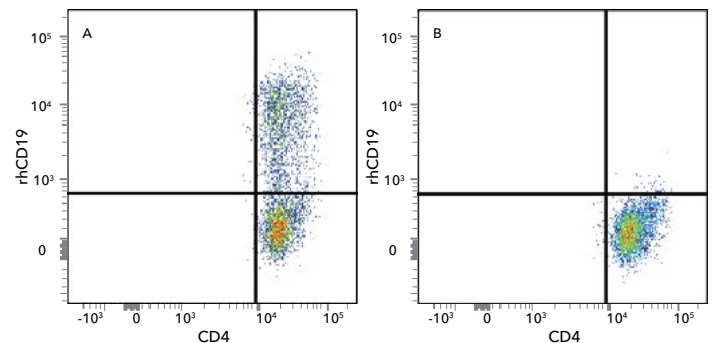
Watch our webinar, [Challenges of Analyzing ATMPs](#), to learn about the complexities of analyzing cell products as you scale up and scale out.



FLOW CYTOMETRY

We offer thousands of conjugated primary antibodies for flow cytometry as well as custom antibody conjugation with nearly 20 fluorophores.

- [Custom Antibody Services](#) - development, conversion to recombinants, antibody engineering, and GMP-grade
- [Fluorescent-Labeled Recombinant Proteins](#) - direct-labeled receptor ligands to verify CAR expression and antigen specificity



Analysis of CD19 CAR expression on human T cells before (A) or after (B) transduction with a human CD19 CAR. Cells were stained with human CD19 Atto 647N-conjugated protein.

Visit | bio-techne.com/methods/flow-cytometry

IMMUNOASSAYS FOR CELL PHENOTYPE TESTING

Confirm the secretory profile and surface marker expression of your cell product. At the core of each our immunoassays are R&D Systems™ antibodies and proteins, backed by over 30 years of experience designing, testing and optimizing immunoassay kits.

- [Luminex® Assays](#) - quantitative multianalyte detection
- [Quantikine™ ELISA Kits](#) - exhaustively tested for superior performance and reproducibility
- [Simple Plex™ Automated ELISAs](#) - quantitation of cytokine secretion profiles in <1 hour with 4+ logs dynamic range
- [Simple Western™](#) - automated, capillary-based immunoassays and size assays
- [Custom Assay Services](#) - assay development, optimization, and translation to automated platforms



Visit | bio-techne.com/methods/immunoassays

PRODUCT PURITY TESTING

Ensure that your final product meets purity specifications by monitoring contamination and heterogeneity.

Micro-Flow Imaging™ (MFI) provides image-based analysis of subvisible particle counts and morphology. MFI discriminates between protein aggregates, oil droplets, bubbles, and other contaminants.

- Up to 150 µL/minute at 900,000 particles/mL
- Bot1 Autosampler for up to 90 samples per run
- High-resolution images with 85% sampling efficiency

Single-Cell Western quantitates protein expression for profiling cell heterogeneity. Milo™ enables thorough monitoring of key molecules in cell therapy products to meet your purity requirements.

- Analysis of ~1000 single cells in a single run
- Up to 12 protein analytes per cell



Bio-Techne believes in the power of partnerships. We have joined with Fresenius Kabi and Wilson Wolf to bring you ScaleReady™ for powerful and versatile immune cell manufacturing.

ScaleReady brings cell and gene therapies to life by streamlining manufacturing processes across cell culture, cell activation and expansion, gene editing, and cell processing.

Learn more at ScaleReady.com





WHEN YOUR WORK DEMANDS
UNIQUE SOLUTIONS,
TURN TO BIO-TECHNE'S
DECADES
OF PRODUCT
DEVELOPMENT
LEGACY

View our updated guide for
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