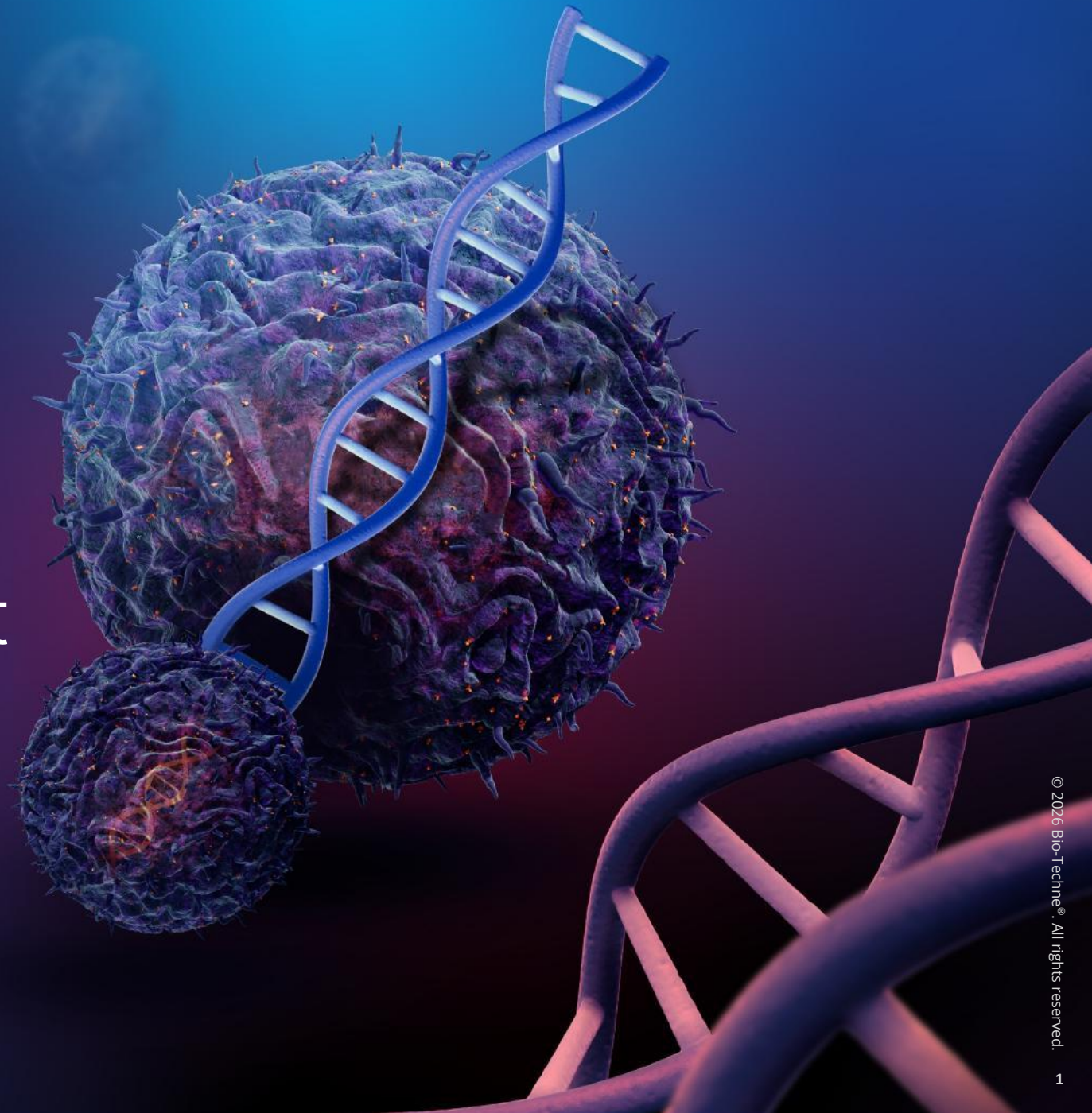
bio-techne®

Next gen tools for cell therapy manufacturing: Addressing key reagent challenges



David Hermanson, PhD
Director, Cell Therapy Product Management
Phacilitate ATW Feb 11th, 2026

Safe Harbor

CAUTIONARY STATEMENTS

This presentation contains “forward-looking statements” within the meaning of the federal securities laws. Except for historical information contained herein, the statements in this presentation are forward-looking and made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements made herein relate to, among other things, future sales, earnings, return on equity, cost savings, process improvements, free cash flow, share repurchases, capital expenditures, acquisitions, benefits of investments and partnerships, business strategies, financial results and other matters. Such statements can be identified by words such as: “expected,” “expects,” “expect,” “forecast,” “would,” “estimate,” “will,” or similar references to future periods.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results could differ materially from those stated or implied in the forward-looking statements. For a list of factors, risks and uncertainties which could make our actual results differ from expected results, please see our latest Annual Report on Form 10-K. We undertake no obligation to update any forward-looking statement, whether written or oral, as a result of new information, future developments or otherwise. This presentation also contains non-GAAP financial information. Management uses this information in its internal analysis of results and believes this information may be informative to investors in gauging the quality of our financial performance, identifying trends in our results and providing meaningful period-to-period comparisons. For definitions of applicable non-GAAP financial measures and reconciliations of non-GAAP financial information to GAAP financial information, see the Reconciliations of GAAP to Non-GAAP Financial Measures included in the Company’s financial reports on Forms 10-Q and 10-K and related press releases.

Committed to Innovations in Cell Therapy

History

50-year legacy of quality cytokine development and manufacture

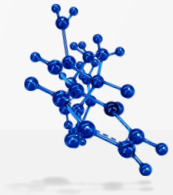
600 GMP customers globally, and growing

Partnered with ~100 clients submitting INDs through Phase III trials

Investments

Dedicated GMP protein **&** small molecule production facilities

ScaleReady™



Potency Assays

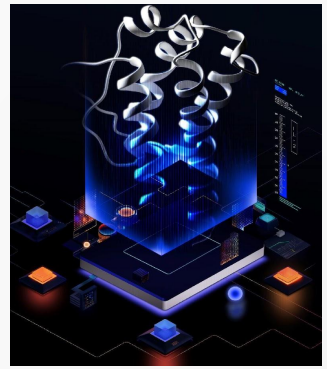
Enabling automated ELISA for cytokine secretion assays with Ella™

Reagent Delivery

Cytokine addition simplified with ProPaks™

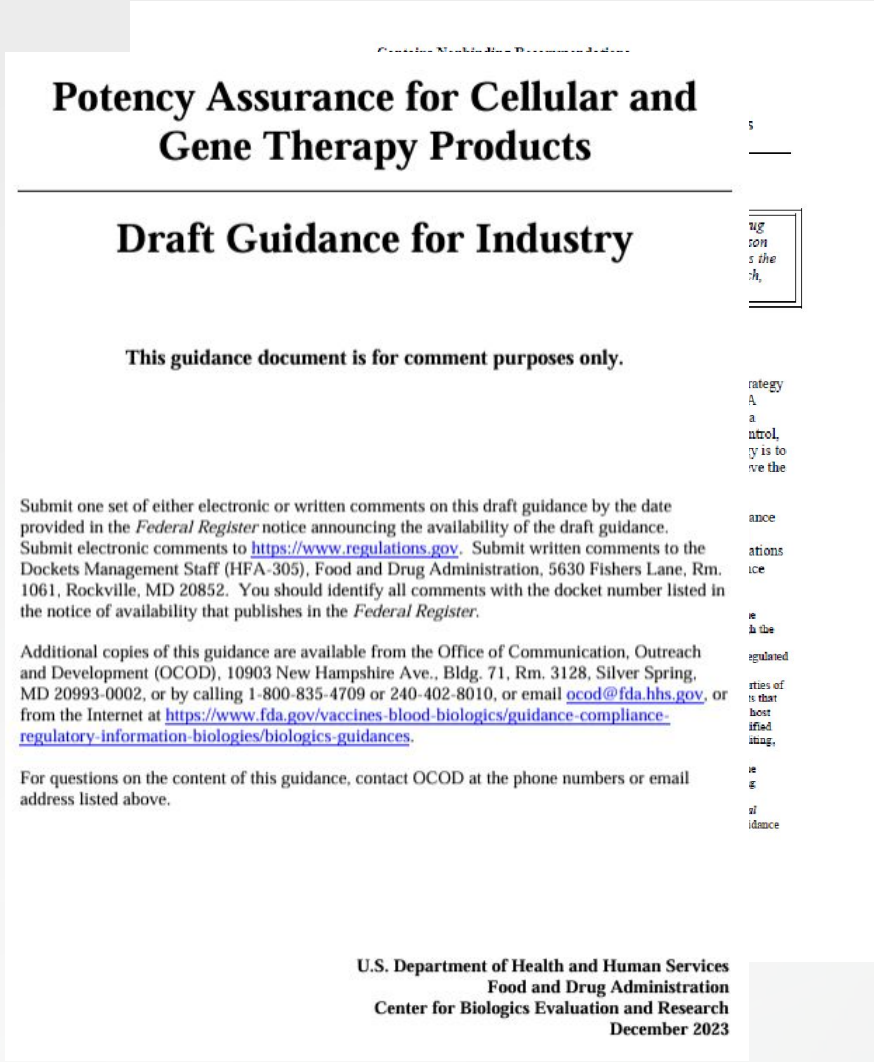
Reagent Future

Simplifying reagent logistics through purposeful innovation with AI Modified Proteins



Keys to Potency Testing

- Start early and collect data throughout process development
- Define your MOA as thoroughly as possible
- Design an assay that can quantitate a potency-related CQA



Potency Assurance for Cellular and Gene Therapy Products

Draft Guidance for Industry

This guidance document is for comment purposes only.

Submit one set of either electronic or written comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologies/biologics-guidances.

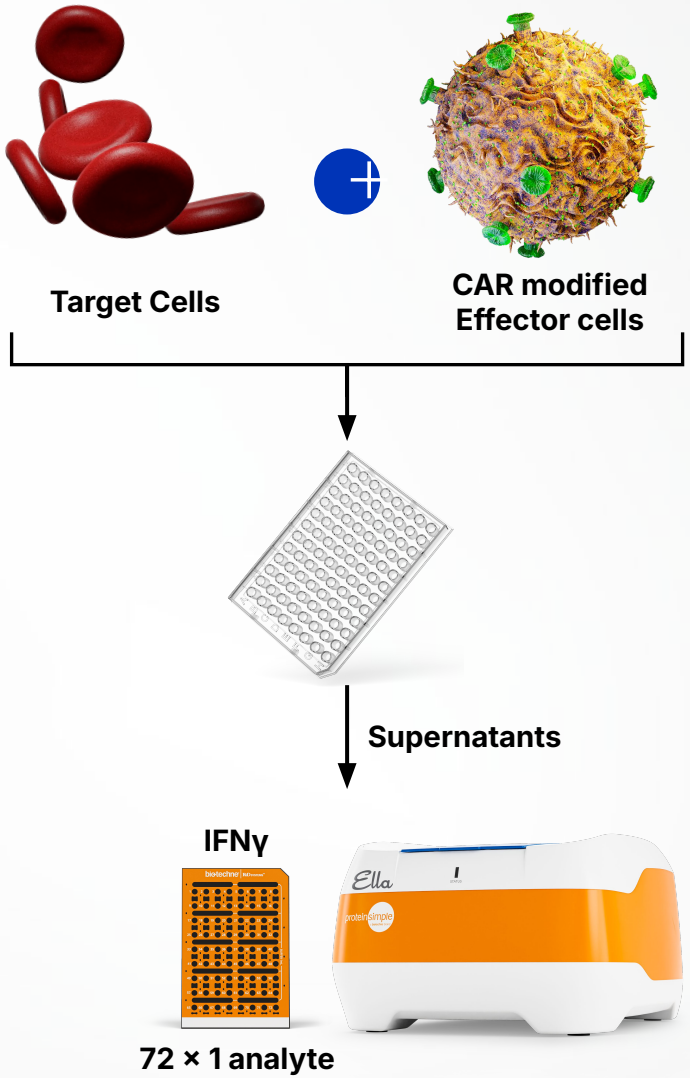
For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

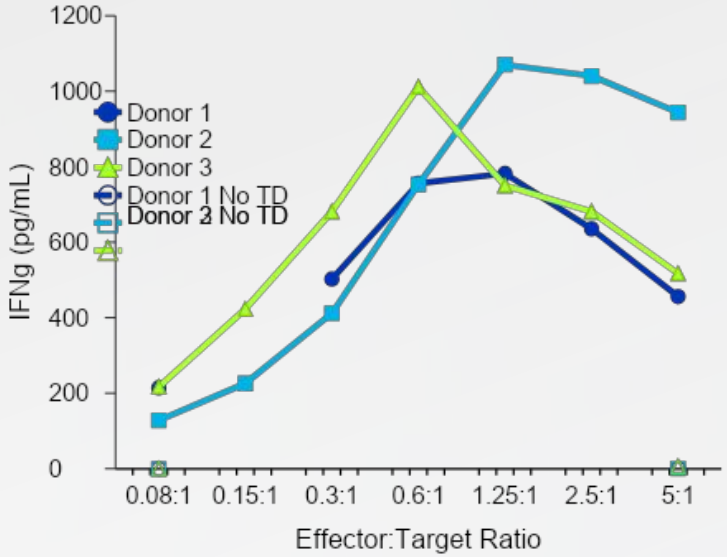
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
December 2023

Potency Testing with

An Automated ELISA

Ella™



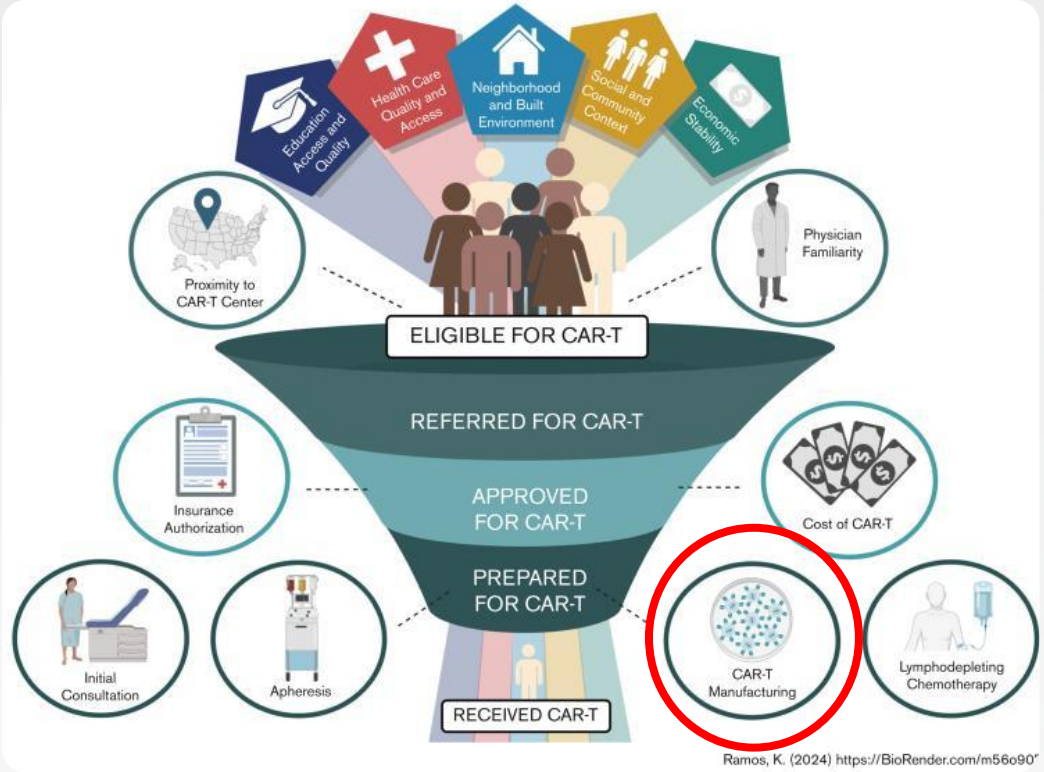


- CD19-transduced T cells were incubated overnight with Nalm-6 tumor cells at the indicated E:T ratios
- Supernatants were collected and IFNγ levels were measured by Ella
- Result: Clear IFNγ detection at all E:T ratios with less than 30 minutes of hands-on time

<90 minutes from sample to results
~300 human analytes available

Addressing the Patient Treatment Gap is Critical to the Future of Cell Therapy

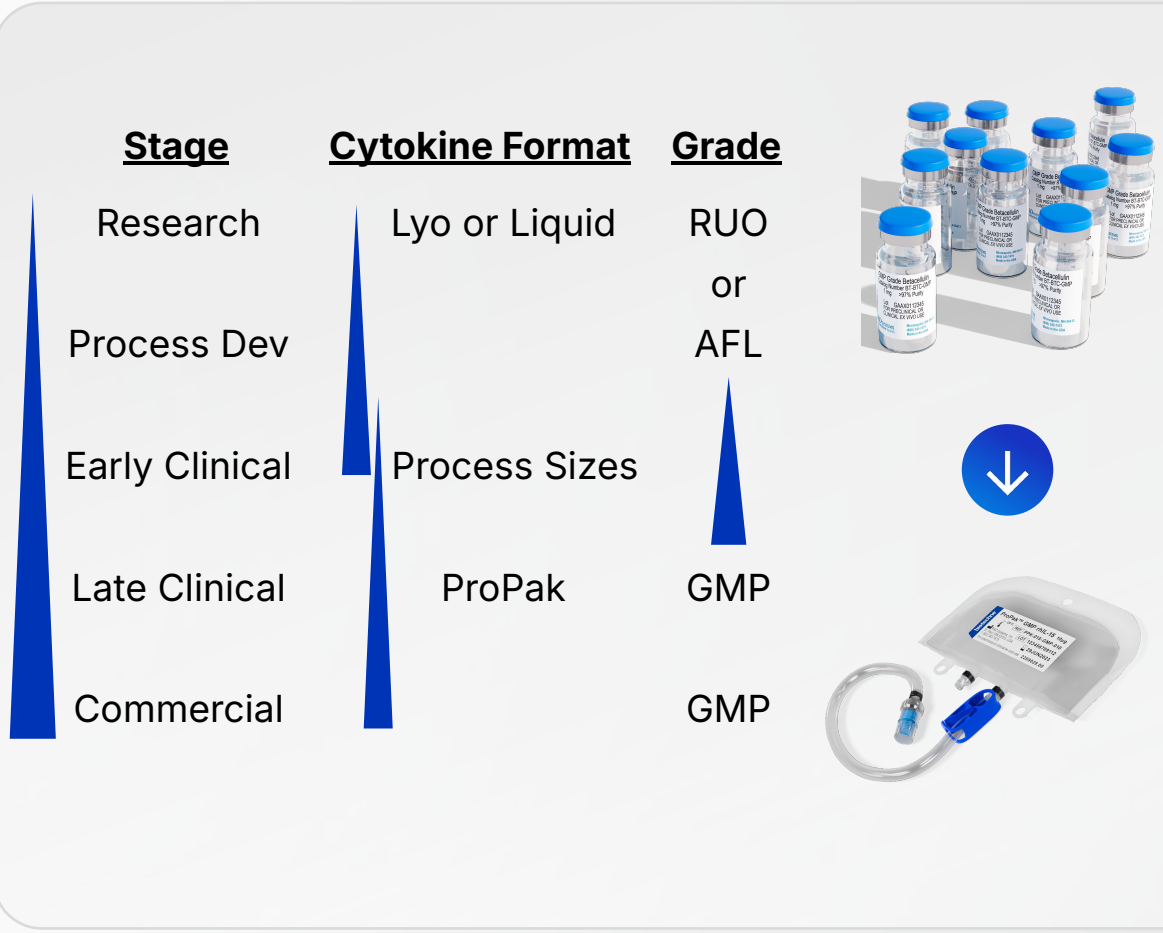
- Far fewer patients receive CAR T cell therapy than could benefit
- Complexity, cost, and failure rates associated with CAR T cell manufacturing are a major contributor
- Commercial success is dependent on creating a simple and effective manufacturing process



Blood Adv. 2025 Jan 28;9(2):436–438. doi: 10.1182/bloodadvances.2024015013

Transforming your Cytokine Supply into a Strategic Advantage

- Manual cytokine delivery remains a critical gap in “closed system” cell therapy manufacturing processes.
- ProPaks contain R&D Systems GMP cytokines prepackaged in ready-to-use weldable bags.
- Simplify reagent handling with made-to-order process sized lyophilized, liquid, or ProPak cytokines.



ProPak™ GMP Cytokines

Closed System Cytokine Delivery
for Cell Therapy Manufacturing

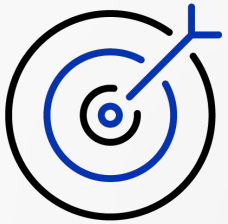
Improving manufacturing scale readiness and regulatory confidence

- **Future proof manufacturing** with consistent, validated materials that minimize comparability gaps.
- **Strengthen Regulatory Position**, backed by full traceability, DMF filings, and global compliance support.
- **Decrease clean room time & reduce risk** with streamlined manufacturing in closed systems.

Cell Therapy Developers Choose ProPak GMP Cytokines

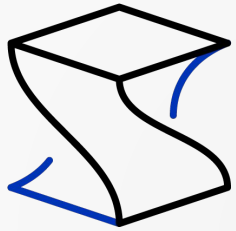
Validation

Supports both autologous T cell therapy and TIL or allogenic workflows with regulatory confidence



Process-sized Flexibility

Made-to-order option to get the exact amount needed



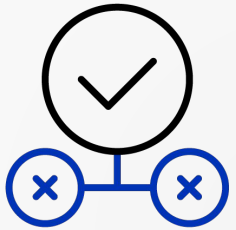
Cost Efficiency

Reduces operator time and cytokine waste

Enables work in lower grade clean room environments

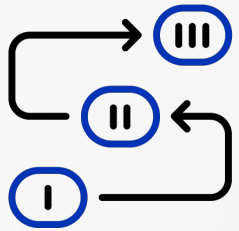
Derisked Manufacturing

Eliminates errors in reconstitution or aliquoting and reduces contamination risk for more consistent product quality



Simplified Workstream

Minimizes manual manipulation steps and simplifies batch records



Addressing the Problems of Today Using the Reagents of Tomorrow

- Scaling up to commercialization requires complex logistics and storage.
- What if the biological reagents used in cell therapy manufacturing could be optimized using AI design?

Addressing Key Challenges in Cell Therapy through AI Modified Proteins: Engineering IL-2

Manufacturing Complexity

Maintained Activity Over a Longer Duration

Problem:

Labor and cleanroom time dedicated to replenishing cytokines in culture

Solution:

- Engineer stability into cytokines to avoid replenishment altogether

Logistics

Increased Stability Alleviates Cold Chain Storage

Problem:

Cold storage requirements carry inherent risk for critical raw materials at commercial scale

Solution:

- Engineer stability into cytokines enabling room temperature storage and removing cold chain risk

Manufacturing Failures

Increased Performance Reduces Cell Mfg. Risk

Problem:

Failure to achieve cell dose for therapies: unable to meet cell expansion and time requirements

Solution:

- Engineered cytokines provide consistent stimulus and improved expansion of TILs

Designed For Improved Patient Outcomes

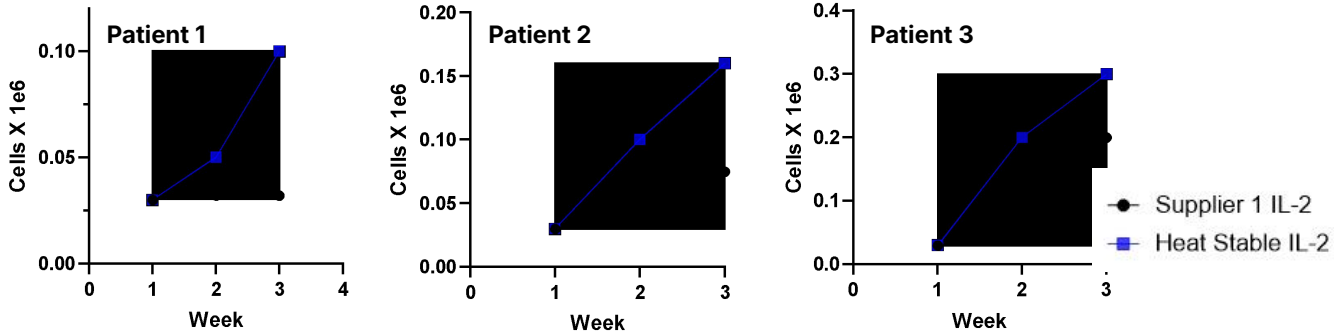
Catalog Number: **BT-002HS**

Improving Cell Expansion

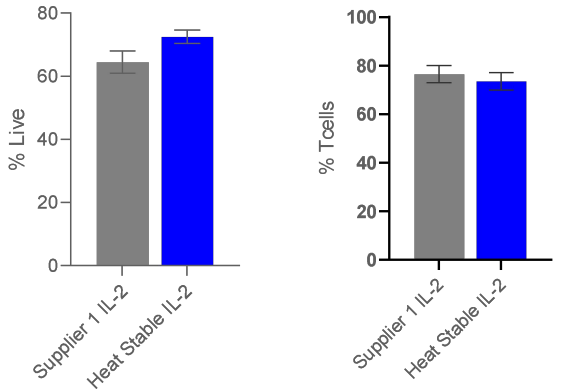
- **Importance:** Failure to expand cells leads to failed manufacturing runs and higher costs
- **Problem:** "A significant number of TIL samples derived from patients fail due to their inability to reach sufficient cell numbers during the initial TIL outgrowth."

  -Branden Moriarity; Associate Professor, Division of Pediatric Hematology and Oncology U of MN
- **Innovation Solution:** AI modified IL-2
- **Impact:** Fewer manufacturing failures leads to more patients helped and improved

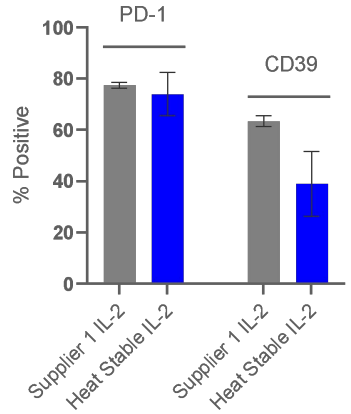
Result: IL-2 Heat Stable protein outperforms competitor IL-2 in metastatic ovarian cancer TILs



Result: Similar Viability and Cell Composition



Result: No Negative Effect on Exhaustion



Data provided with permission by Moriarity and Webber labs at University of Minnesota

Bio-Techne as Your Strategic Partner

Solving Today's Challenges

Applying technology to provide simple to use innovations

Potency Assays

- Run automated ELISAs with Simple Plex assays on Ella to reduce labor costs and ensure consistent results across sites, instruments and operators

Reducing Manufacturing Complexity

- Made-to-order processed sized amounts
- Different formats to enable easier delivery
- Fully closed option with ProPak GMP Cytokines
- Solve logistical problems of reagent storage with AI-modified proteins
- Improving cell culture outcomes

Applying Innovations to All Cell Therapies

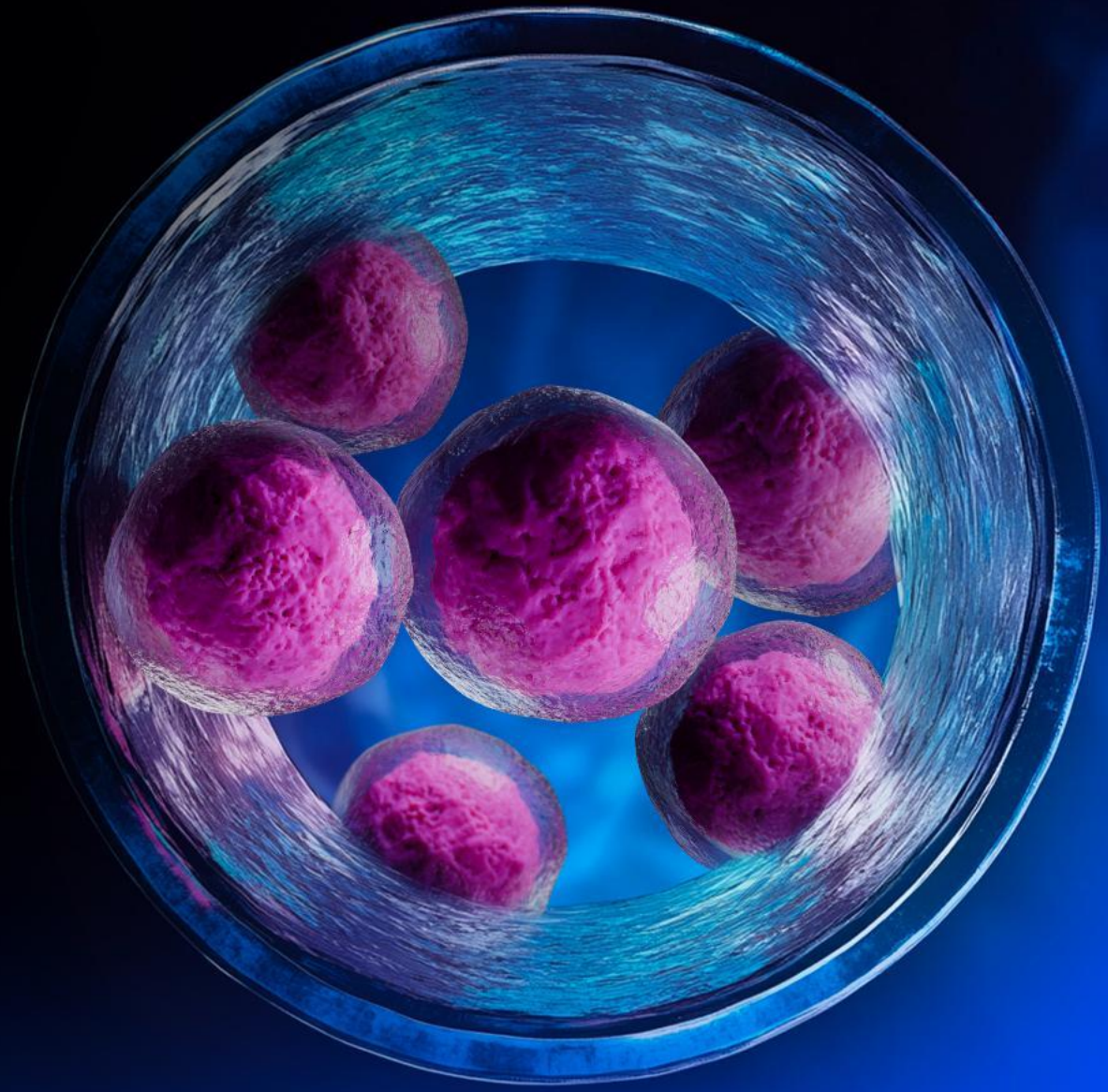
Simple Plex is also being applied for residual protein monitoring and to ensure proper dosing of cytokines during cell expansion and differentiation phases

Supplying trusted, high-quality cytokines and small molecules to PSC-derived cell therapy & immune cell therapy developers

Expanding our menu of fit-for-purpose cytokines and reagents

Partnering to provide innovative solutions in cell culture to allow developers to focus on providing the best cell therapy

Thank You



FOR MORE INFORMATION:

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Visit booth #512 for questions, to share your manufacturing hurdles, or just to chat!

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