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Assay Insider

WINTER 2026 // VOL.1 ISSUE 4

CELL & GENE THERAPY

Accelerating Innovations

The Next Frontier
Immunoassays that scale with CGT development

Smarter QC
Faster IFN-γ data you can trust

90 Minutes to Clarity
Fast, precise CAR-T potency data

Assay Insider

Winter 2026 // Volume 1, Issue 4

Cell & Gene Therapy: Accelerating Innovations

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Powering the Promise of Cell and Gene Therapies

Precision Analysis for the Next Frontier

Cell and gene therapies (CGT) are advancing at remarkable speed—but progress in this field is only as strong as the data behind it.

As therapies move from discovery into clinical development and manufacturing, the ability to measure biological activity with speed, precision, and reproducibility becomes a defining factor for success. In a space where every sample is precious and every decision carries downstream impact, robust analytical tools are no longer optional—they are foundational.

Precision Is Imperative

Unlike traditional biologics, cell and gene therapies are living systems shaped by inherent variability. Patient-to-patient differences, viral vector performance, and engineered cell behavior can all influence therapeutic outcome. As programs scale, developers must balance innovation with consistency—delivering reliable results while controlling cost, minimizing risk, and meeting regulatory expectations.

This is where precision analysis plays a critical role. From viral vector quantification and transduction efficiency to immune monitoring, cytokine profiling, and functional assessment, accurate and reproducible measurement underpins confidence at every stage of the CGT development workflow. Immunoassays, in particular, have become essential tools for translating biological complexity into actionable insight.

Feature continues →

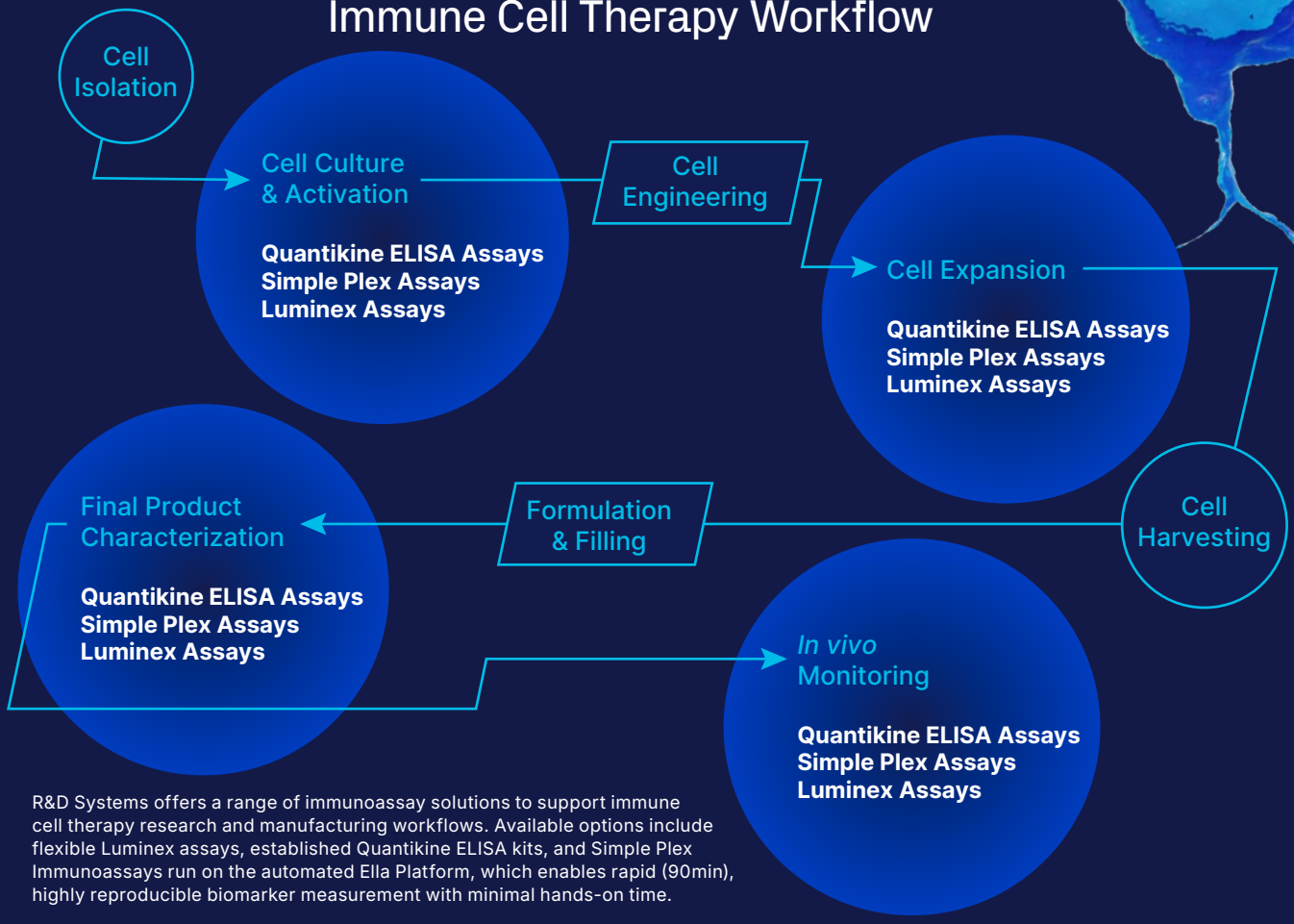
What the Data Must Deliver

As CGT continues to evolve, researchers require analytical solutions that can keep pace with rapid innovation while supporting real-world constraints. Key needs include:

- Reliable, reproducible data to support confident decisions across development stages.
- Scalable performance that bridges discovery, translational research, and manufacturing.
- Flexibility and breadth to adapt to emerging modalities, targets, and workflows.
- Operational efficiency to accelerate timelines without compromising quality.

Meeting these demands requires more than sensitivity alone—it requires platforms designed for consistency, standardization, and long-term scalability.

Immune Cell Therapy Workflow



R&D Systems offers a range of immunoassay solutions to support immune cell therapy research and manufacturing workflows. Available options include flexible Luminex assays, established Quantikine ELISA kits, and Simple Plex Immunoassays run on the automated Ella Platform, which enables rapid (90min), highly reproducible biomarker measurement with minimal hands-on time.

Tools that Turn Complexity into Confidence

Bio-Techne delivers a comprehensive portfolio of immunoassay solutions built to meet the analytical demands of cell and gene therapy—combining sensitivity, reproducibility, and flexibility across complementary platforms.

Simple Plex™ Immunoassays on the Ella™ Platform provide high-sensitivity, automated quantitation with minimal hands-on time. Sub-picogram detection and rapid turnaround support viral vector measurement, cytokine analysis, and immune cell characterization with confidence.

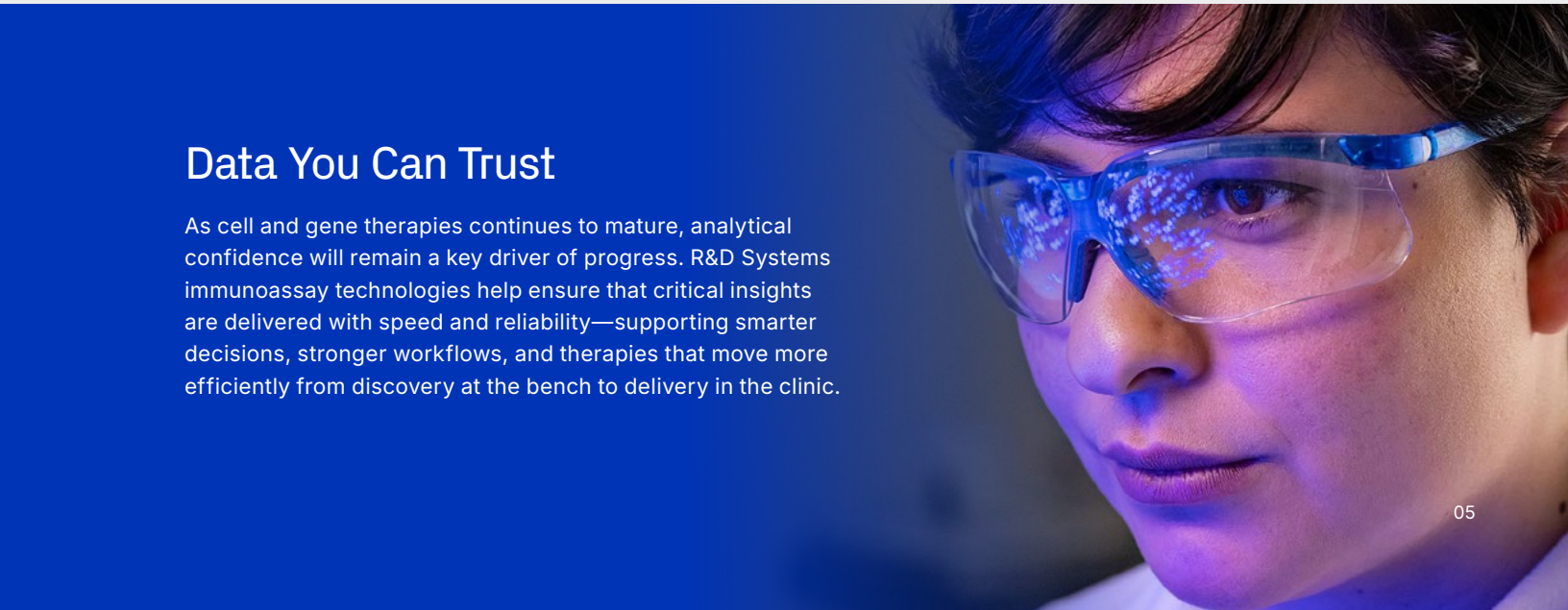
R&D Systems Luminex® Multiplex Immunoassays enable simultaneous measurement of up to 50 analytes, conserving valuable samples while delivering high-throughput, information-rich data. Available panels support T cell characterization, immune monitoring, and bioprocess optimization.

R&D Systems™ ELISA Kits—including Quantikine™, QuicKit™, and DuoSet® formats—offer trusted performance across more than 1,000 validated targets, supporting every phase of CGT development from early research through quality control.

Together, these platforms empower researchers to select the right balance of throughput, sensitivity, and flexibility—each grounded in R&D Systems Immunoassays long-standing commitment to data quality and reproducibility.

Data You Can Trust

As cell and gene therapies continues to mature, analytical confidence will remain a key driver of progress. R&D Systems immunoassay technologies help ensure that critical insights are delivered with speed and reliability—supporting smarter decisions, stronger workflows, and therapies that move more efficiently from discovery at the bench to delivery in the clinic.



Featured Resource

Download the full resource to explore how Simple Plex Assays are accelerating potency testing and strengthening analytical strategies for immune cell therapies.

Explore the Full Data

Scan the QR Code or Visit:
resources.bio-techne.com/bio-techne-assets/images/literature/qc-release-testing-ifn-gamma-ella-2.pdf

A Better Way to Measure CAR-T Performance

Potency testing is a cornerstone of CAR-T development—and one of the most scrutinized steps in releasing a gene-modified cell therapy. A new featured resource breaks down how Simple Plex Assays provide a fast, precise, and scalable way to measure interferon-gamma (IFN-γ), one of the most critical functional readouts for immune effector cells.

Why IFN-γ Matters

Across FDA-approved CAR-T products, IFN-γ secretion remains a primary marker of biological activity, correlating closely with antigen-specific cytotoxicity and anti-tumor response. But traditional cytotoxicity methods—flow-based or luciferase-based—can be time-consuming, variable, and limited in what they reveal about the effector cells themselves.

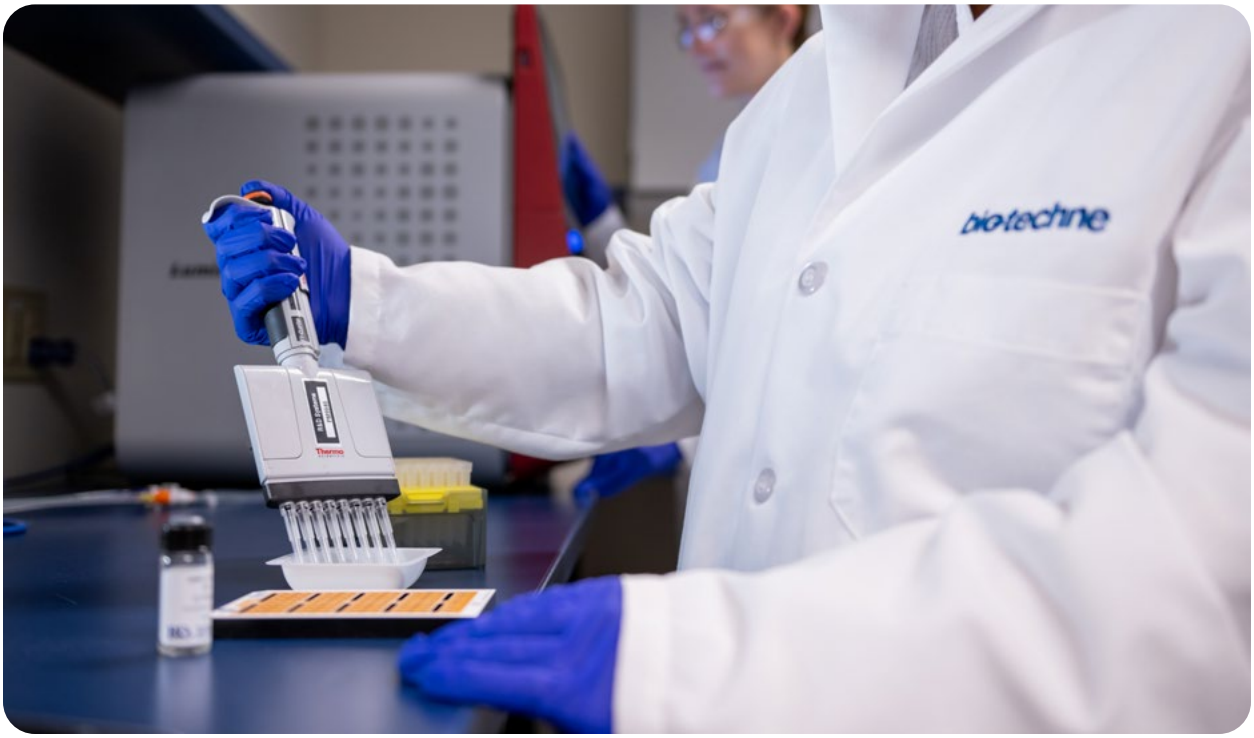
Precision Data in 90 Minutes

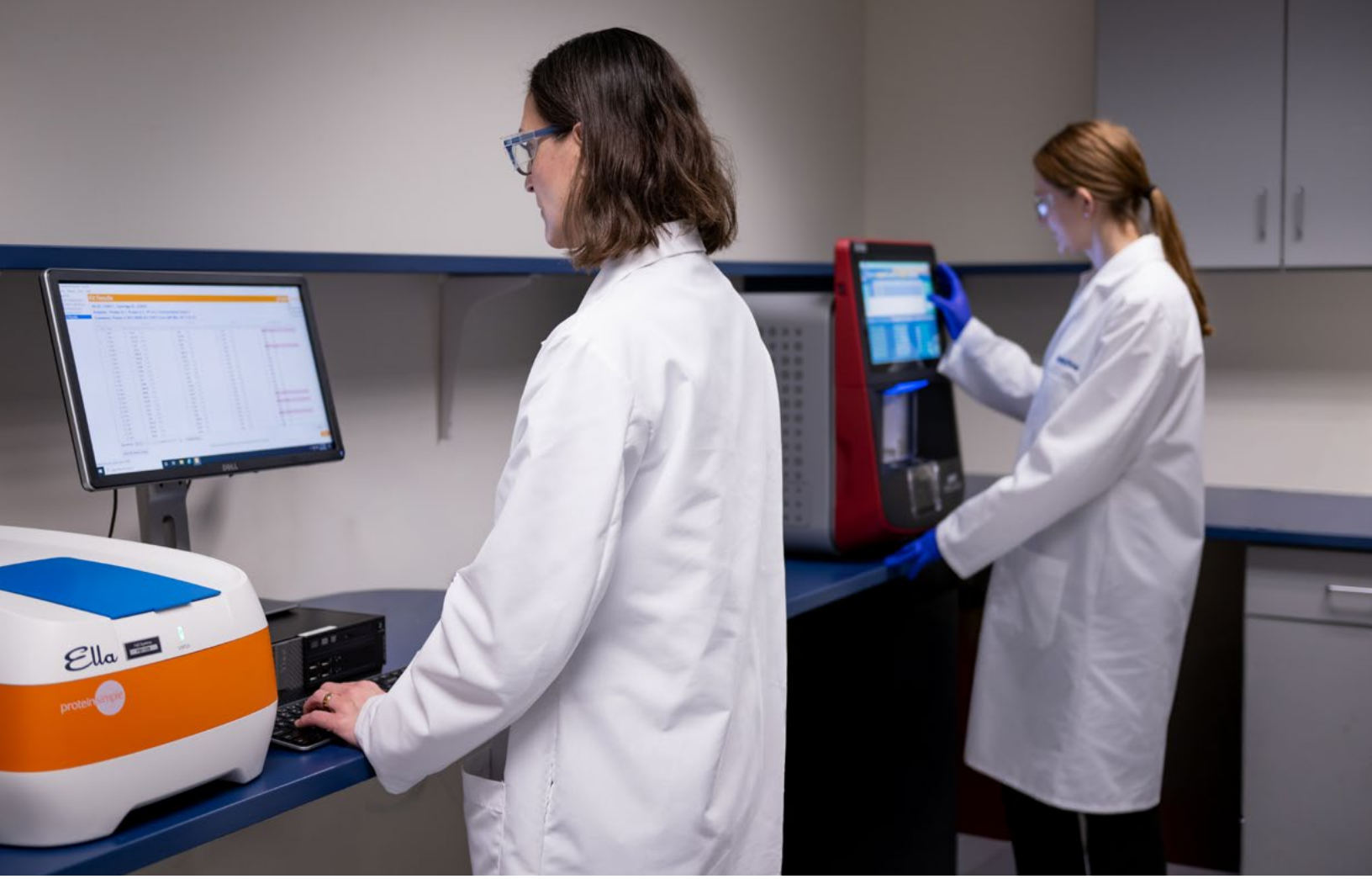
The Simple Plex IFN-γ Assay offers a streamlined, automated workflow that delivers high-quality potency data in just 90 minutes. Using microfluidic cartridges and pre-validated protocols, the platform minimizes hands-on steps and user variability—ideal for supporting growing patient volumes in cell therapy manufacturing.

In co-culture studies with Nalm-6 and K562 target cells, IFN-γ secretion closely mirrored CAR-T cell specificity and cytotoxicity across donors and E:T ratios. Precision studies further demonstrated exceptional reproducibility, with broad dynamic range (0.17–4000 pg/mL), an LOD of 0.05 pg/mL, and low CVs in both intra- and inter-assay formats.

Built for Regulatory-Ready Performance

Validated to meet FDA expectations for precision, accuracy, specificity, and robustness, Simple Plex Assays provide a dependable, quantitative potency readout that complements orthogonal functional assays. The result: clearer insight into CAR-T activity, faster turnaround, and greater confidence across development and manufacturing.





Technical Corner

More Than One Signal: Redefining How Immune Cell Function Is Measured

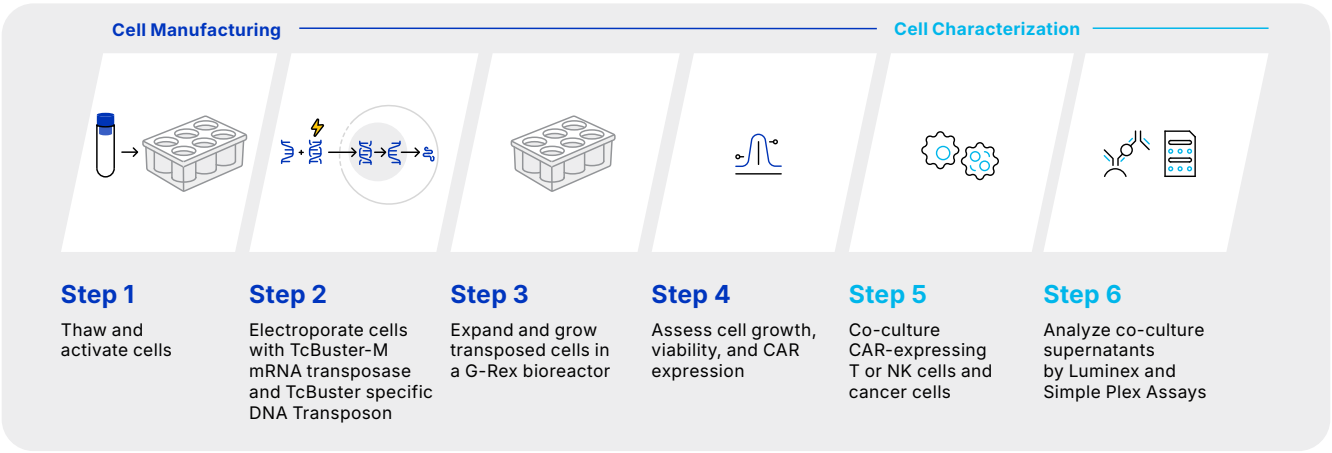
Potency testing remains a critical—and evolving—challenge in immune cell therapy development. While most current assays rely on single-analyte IFN-γ readouts, regulators and developers alike are pushing toward more comprehensive, mechanism-driven characterization of CAR-T and CAR-NK cell function.

This new application note presents a high-throughput immunoassay workflow designed to move beyond one-dimensional potency measurements. By combining R&D Systems Luminex® Assays with Simple Plex Assays, the approach enables broad secretome discovery alongside sensitive, reproducible validation of key functional markers.

Using CD19-CAR-T and CAR-NK cells engineered with the Bio-Techne TcBuster™ Transposon System, the study profiles secretion of 123 cytokines, chemokines, growth factors, and cytotoxic effector proteins during antigen-specific killing. The results reveal distinct secretion signatures between CAR-T and CAR-NK cells, donor-to-donor variability in functional output, and additional biomarkers—beyond IFN-γ—that more fully reflect immune cell potency and mechanism of action. Targeted Simple Plex assays then validate and extend these findings, demonstrating strong cross-platform correlation and sensitive quantitation of low-abundance proteins.

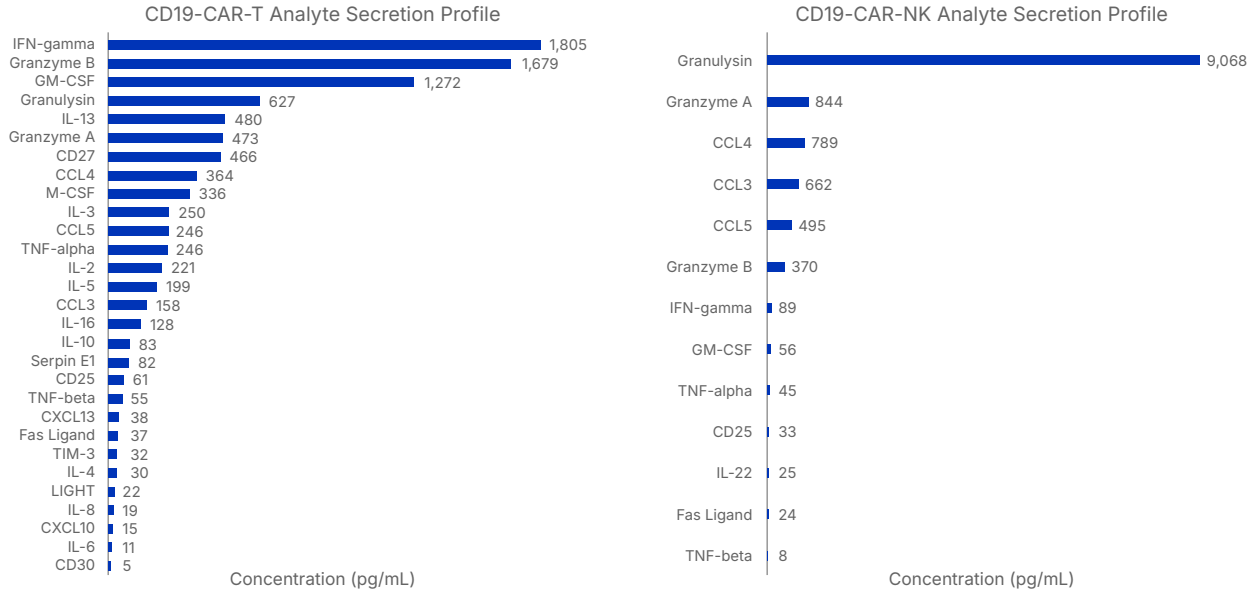
Together, this featured resource outlines a practical path from broad discovery to focused, multi-analyte potency assays—supporting deeper functional insight, better assay design, and more informed decision-making across cell therapy development.

From the Application Note:



R&D Systems pipeline for editing and characterizing cells to be used in immune cell therapies.

Secretion profiles of CD19-CAR-T and –NK cells when co-cultured with Nalm-6 cells were established using R&D Systems Assays for Luminex Instruments.



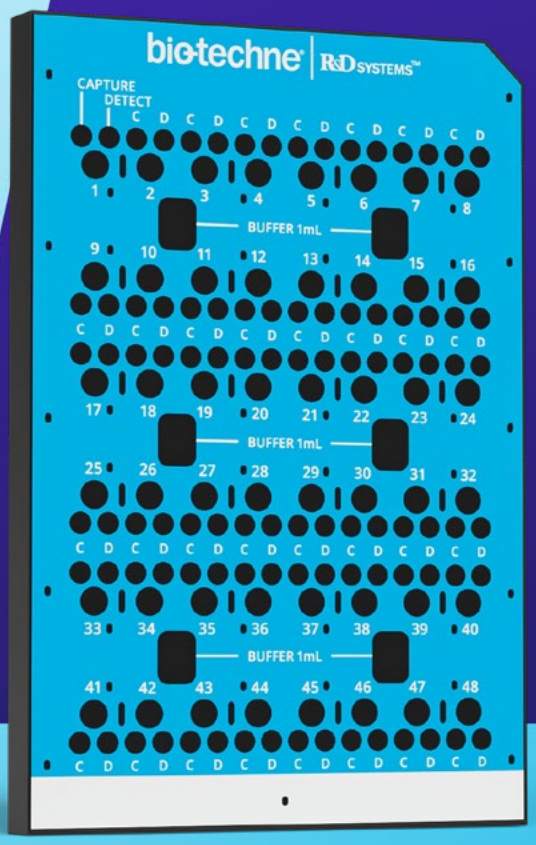
123 proteins were screened using R&D Systems Luminex Assays for presence in supernatant samples collected from CD19-CAR-T and –NK killing assays. Analyte secretion profiles were curated and ranked based on average concentrations measured across three T cell and three NK cell donor samples. Sample concentrations from the largest effector: target cell ratio tested (5:1 for the CD19-CAR-T cells, 3:1 for the CD19-CAR-NK cells) were averaged among the three donor sets to include low-abundance proteins and generate the most comprehensive analyte secretion profile.

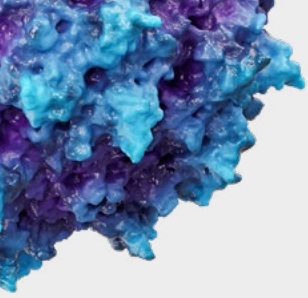
Download the full application note to explore the data, workflow, and implications for CAR-T and CAR-NK potency assessment.

Learn More

Scan the QR Code or Visit:
bio-techne.com/viral-titer-assays

New Products





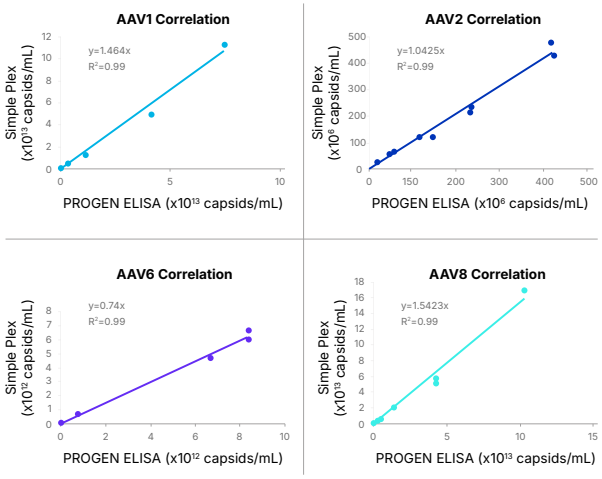
Broader AAV Coverage. Same 90-Minute Workflow.

As AAV programs expand, so does the need to measure more serotypes—without adding complexity to already tight workflows. With the new Simple Plex AAV3 and AAV9 Assays on the Ella platform, teams can extend capsid titer quantification to additional serotypes while maintaining the same fast, automated, and standardized approach they already rely on. Combined with the existing AAV1, AAV2, AAV6, AAV8, and HIV p24 assays, the Simple Plex AAV Assays support broader program coverage without changing how you work.

Simple Plex AAV Assays are designed for fast, automated, and reproducible AAV capsid titer quantification. Each assay comes fully preloaded with reagents and a validated standard curve—reducing hands-on time, eliminating manual standard preparation, and minimizing operator-dependent variability.

Powered by PROGEN™ serotype-specific antibodies, the Simple Plex AAV Assays deliver the specificity researchers trust, paired with the efficiency of walk-away automation. From setup to results in under 90 minutes, these assays support process development, viral vector characterization, and release testing with confidence and consistency.

With the addition of AAV3 and AAV9, the Simple Plex AAV Assays continues to grow—helping teams scale faster while maintaining reliable, high-quality data across gene therapy workflows.



Linear correlations of Simple Plex AAV Assays and PROGEN AAV ELISAs. The aggregated Simple Plex and PROGEN ELISA data was plotted and a linear fit was applied to the data for each AAV serotype. The Simple Plex AAV Assays are corelated with the corresponding PROGEN ELISAs with an R^2=0.99 (2a-2d). The data shows the quantitative range of both assays overlap.

Learn More

Scan the QR Code or Visit:
bio-techne.com/resources/instrument-applications/simple-plex-viral-titer-assays

More Ways to Protect Your Investment

Your instrument is critical to keeping work on schedule—and downtime isn't an option. That's why we've enhanced our instrument service and support plans, giving you more flexible ways to protect your investment, reduce interruptions, and maintain performance over the long term.

Bio-Techne service plans are built to support consistency and confidence across academic, government, and industry labs. Each plan includes an annual preventive maintenance visit to keep instruments operating to manufacturer specifications, backed by experienced service engineers who resolve issues quickly and efficiently.

For teams looking for maximum protection, expanded Platinum coverage is now available at the time of purchase. This option delivers comprehensive, uninterrupted support from day one, including on-site service, full parts and labor coverage, priority scheduling, and preventive maintenance—helping minimize risk and keep your research moving.

Together, these enhancements provide more choice, stronger protection, and greater peace of mind—so you can focus on your research, not your instrument.

Learn More

Scan the QR Code or Visit:
bio-techne.com/resources/instrument-services

Instrument Service Plans:

PLATINUM AT PURCHASE offers exceptional value by delivering uninterrupted Platinum-level service from the moment your instrument is installed. The plan enhances your first-year warranty to full on-site Platinum coverage and continues with a 12-month Platinum service contract, ensuring two years of top-tier support. With unlimited on-site service, full coverage of repair parts, labor, and travel, and one annual preventive maintenance visit with all materials included, this plan provides complete peace of mind. Priority scheduling minimizes downtime, while included advance training tokens support advanced skill development for your team.

PLATINUM coverage provides on-site repair labor, travel, and parts, plus an annual preventive maintenance visit. First level priority ensures rapid response and minimal downtime.

GOLD coverage includes on-site repair labor and travel, plus an annual preventive maintenance visit. Repair parts are quoted and purchased separately.

SILVER provides and annual on-site preventive maintenance visit. All repair labor, parts, and travel and quoted and purchase separately.

DEPOT service provides mail-in repair support including repair labor and parts, plus an annual depot PM. Shipping both ways is included.

Coming Soon!

The Luminex® Human Discovery Assay analyte menu is expanding. In spring 2026, 16 new analytes will be added to support rigorous quality testing and characterization, helping teams assess cell therapy potency prior to patient infusion.

New Human Discovery Analytes:

Amphiregulin	PD-L2	FGF-21	Clusterin	TIMP-2	IL-9
CRHBP	COMP	IL-22	Granulysin	TIMP-3	Nectin-2
IL-20	CD21	Perforin	Intelectin-1	TIMP-4	

Assays in Action

Mapping Cytokine Profiles in Human Breast Milk

"We can now handle samples efficiently and screen more cytokines in one shot—without compromising accuracy."

Dr. Tengku Norbaya binti Tengku Azhar
Pusat Asasi, UiTM Cawangan Selangor, Kampus Dengkil, Malaysia

How do environmental exposures influence immune factors in breast milk? Researchers at Universiti Teknologi MARA (UiTM) in Malaysia are exploring this critical question by profiling cytokines in human milk from exclusively breastfeeding mothers exposed to second-hand smoke. Understanding these immune signals may provide important insights into early-life immune development.

To overcome the challenges of working with sensitive, limited-volume milk samples, the research team adopted R&D Systems Luminex Assays. The multiplex approach enabled simultaneous detection of multiple cytokines in a single run, reducing sample handling, preserving analyte integrity, and significantly improving workflow efficiency compared to single-analyte ELISAs.

With streamlined data analysis and improved reproducibility, the team accelerated their research timeline and gained greater confidence in their results—paving the way for new insights into how environmental factors may shape immune composition in human milk.

Read the full case study to learn how multiplex immunoassays are advancing human milk research and supporting high-quality cytokine profiling in complex biological samples.

Read the Case Study

Scan the QR Code or Visit:
bio-techne.com/resources/testimonials/human-milk-cytokine-luminex-malaysia

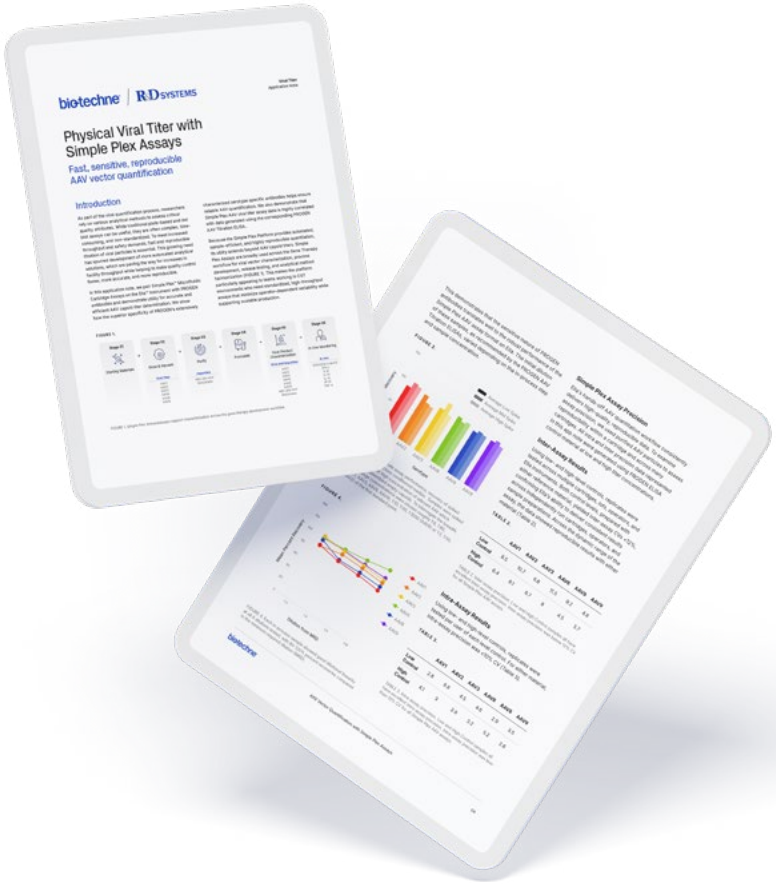
Hot Off the Press

Taking the Manual Work Out of AAV Quantification

As gene therapy programs scale, AAV capsid titer determination needs to be faster, more consistent, and easier to standardize. Traditional viral quantification methods often struggle to keep up, requiring significant hands-on time and introducing variability that can compromise reproducibility across runs and users.

This new application note highlights a streamlined approach using Simple Plex™ AAV Viral Titer Assays on the Ella Platform, paired with PROGEN serotype-specific antibodies. The fully automated, microfluidic workflow delivers sensitive, highly reproducible AAV quantitation in under 90 minutes—reducing manual steps while maintaining continuity with established PROGEN ELISA data and supporting consistent performance across instruments, operators, and laboratories.

With broad dynamic range, strong correlation to industry-standard ELISAs, and excellent precision, this solution supports viral vector characterization, process development, and QC testing across the gene therapy workflow—making it well suited for both research and GMP-aligned environments.



Download the full app note to see how Simple Plex Assays can streamline AAV quantification from development through production.

Explore the Data

Scan the QR Code or Visit:
resources.bio-techne.com/bio-techne-assets/docs/literature/aav-app-note.pdf

We Want to Hear Your Story!

We're looking for inspiring stories to feature in our upcoming newsletter. Whether it's a breakthrough moment, a creative application, or a standout achievement, your story could be the one to motivate and inform others in our community.

Have an amazing success story or unique experience with our products or services? Share it with us!

Submit Your Story Today

Scan the QR Code or Visit:
https://forms.office.com/r/1MXsKgA8qN

Latest Assay Releases

ELISA Kits

Product Name	Catalog Number
Human IL-10 QuicKit ELISA	QK1064
QuicKit Immunoassay Control for Human IL-10	QC319
Human Erythropoietin/EPO Quantikine IVD ELISA Kit	DEP00B
Human NF-L DuoSet ELISA	DY1644-05
Human CD69 DuoSet ELISA	DY2359-05
DuoSet ELISA Ancillary Reagent Kit 1	DY007B
DuoSet ELISA Ancillary Reagent Kit 2	DY008C
DuoSet ELISA Ancillary Reagent Kit 3	DY009C
TMB and Stop Solution Pack	DYTMBS0
Methanesulfonic Acid Stop Solution, 16 x 12 mL vials	DY994B
Methanesulfonic Acid Stop Solution, 250mL	DY994B-250
TMB Substrate Pack	DY999B-250

Luminex Panels

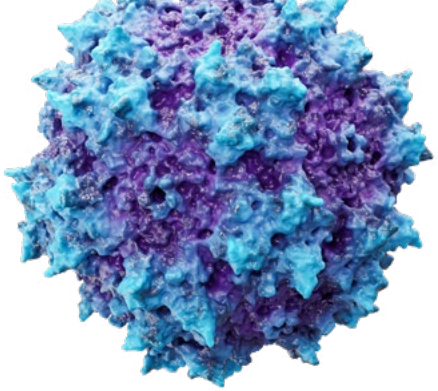
Product Name	Catalog Number
NHP XL Cytokine Performance Panel	LKTM021

Latest Immunoassay Products

Scan the QR Code or Visit:
bio-techne.com/applications/immunoassays/new-product-page

Simple Plex Assays

Product Name	Catalog Number
Simple Plex Ultra-Sensitive Assays	Various
Simple Plex AAV9 Cartridge	SPCKB-OT-015059
Discovery Human Dopa Decarboxylase/DDC	SPCKB-PS-015351
Discovery Human M-CSF R	SPCKB-PS-015350
Discovery Human Pro-Collagen I alpha 1	SPCKB-PS-015353
Discovery Human Angiopoietin-like Protein 7	SPCKB-PS-015352
Discovery Human Serpin F1/PEDF Assay	SPCKB-PS-015287
Human IgG Pan Specific Cartridge	SPCKB-PS-007587
Discovery Human CCL11/Eotaxin Assay	SPCKB-PS-014624
NHP IL-10 Cartridge	SPCKB-NP-014817
Discovery Human Uromodulin Assay	SPCKB-PS-014653
Discovery Human Syndecan-1 Assay	SPCKB-PS-014654
Discovery Human TRANCE/RANK L/TNFSF11Assay	SPCKB-PS-014623
Discovery Human OX40 Ligand/TNFSF4 Assay	SPCKB-PS-014625
Discovery Human Complement Factor D Assay	SPCKB-PS-012122
Discovery Human CCL13/MCP-4 Assay	SPCKB-PS-014652
Discovery Human beta-Defensin-2 Assay	SPCKB-PS-014655
Digoxigenin Open Cartridge	ST01D-OT-006229



Cell and Gene Therapy Crossword

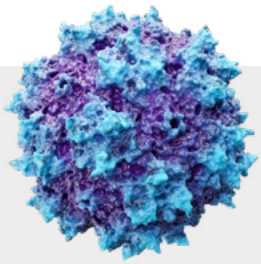
Test your knowledge with this crossword puzzle.

Across

4. Stem cells derived from early-stage embryos
6. Gene therapy aims to treat or prevent these conditions.
7. Type of DNA technology that inspired gene therapy.
8. Approach to gene therapy that involves turning off a mutated gene
10. Condition of a gene after successful gene therapy replacing a defective one.
12. Approach to gene therapy involving replacing a mutated gene with a healthy one.
13. Cells with potential to develop into many different types of cells in the body.
14. Enables the transfer of genes to the inaccessible outer hair cells when introduced into the cochlea.

Down

1. Type of gene therapy involving genetic modifications that can be inherited.
2. Medical technique involving the modification of genes to treat or prevent disease.
3. Unit of measurement for sound, relevant in the context of restoring hearing through gene therapy.
5. Stem cells that exist in the body after embryonic development.
9. Carrier used to deliver genes in gene therapy, often a virus.
11. Alteration in a DNA sequence that gene therapy can potentially fix.
13. Type of gene therapy affecting only non-reproductive cells.



Upcoming Events

Connect with us at upcoming events and discover how Bio-Techne's latest innovations are driving the future of science!

ATW: Phacilitate
February 9-12, 2026

San Diego, CA
phacilitate.com/advanced-therapies-week

WRIB
April 13-17, 2026

Dallas, TX
www.wrib.org

AACR
April 17-22, 2026

San Diego, CA
www.aacr.org/meeting/aacr-annual-meeting-2026

AAI
April 15-19, 2026

Boston, MA
immunology2026.aai.org

ASGCT
May 12-16, 2026

Boston, MA
annualmeeting.asgct.org

Analyte Menu

Check out our comprehensive selection of immunoassays optimized for accurate biomarker quantification.

Simple Plex Menu

bio-techne.com/SimplePlexMenu

ELISA Menu

bio-techne.com/ELISA

Luminex Menu

bio-techne.com/luminex-assays

Contact an Immunoassay Specialist

bio-techne.com/support/sales-support

Crossword Solutions
Across 4. Embryonic 6. Disease 7. Recombinant 8. Inactivation 10. Healthy 12. Replacement 13. Stemcells 14. ANC80
Down 1. Germline 2. Genetherapy 3. Decibels 5. Somaticstemcell 9. Vector 11. Mutation 13. Somatic

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