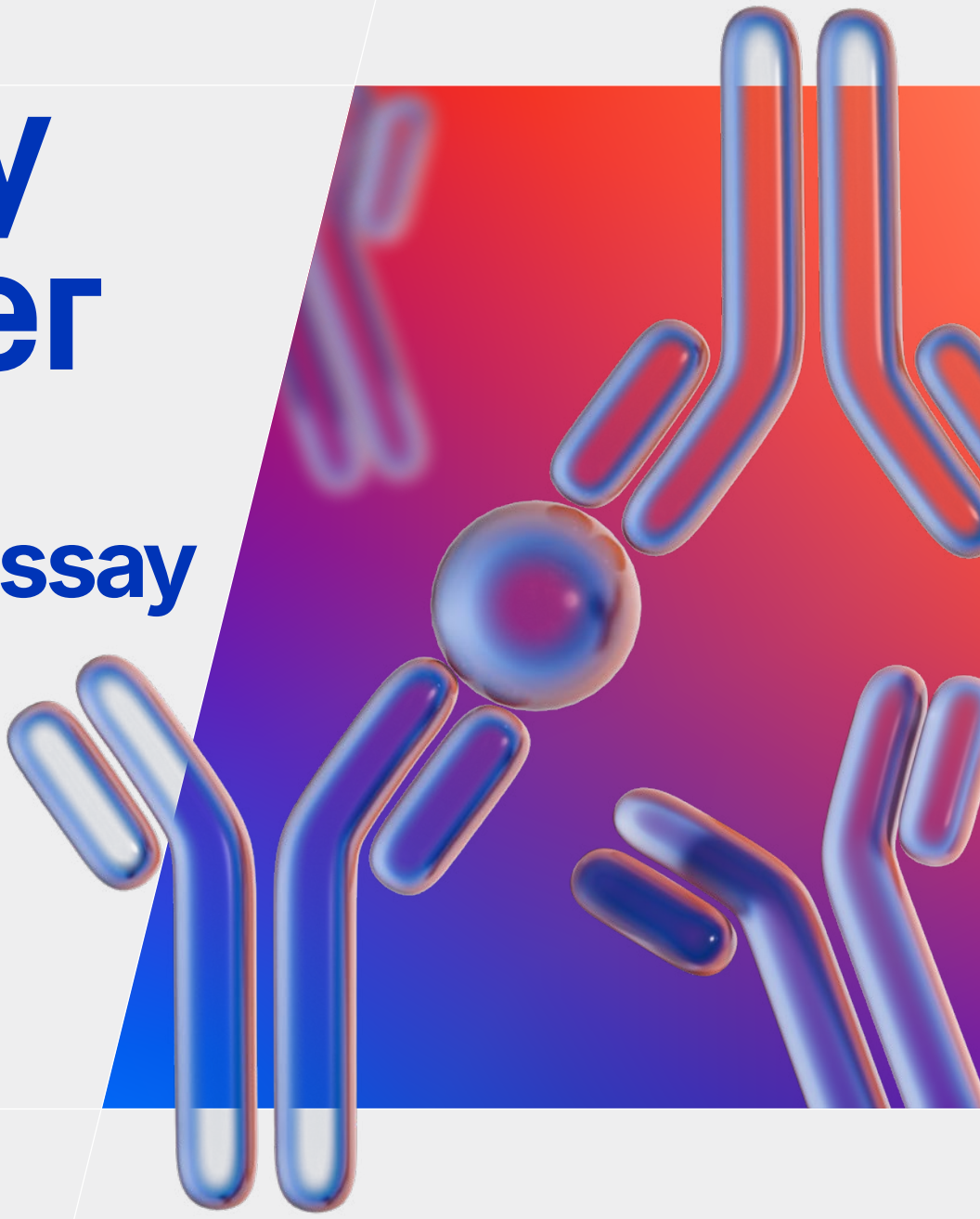
R&D systems™
by bio-techne

Assay Insider

VOLUME 2 ISSUE 1



Immunoassay Quality: *Reliable by Design*

Built on Confidence

Immunoassay quality you can rely on from day one

Designed for Reproducibility

Consistent data across assays, labs, and time

Reducing Variability

Automation that delivers precision without compromise

Assay Insider

Volume 2 Issue 1

Immunoassay Quality: Reliable by Design

Contents

Subscribe to Assay Insider / info.bio-techne.com/assay-insider

Quality *at the Core*

The Foundation of Reliable Immunoassays

In life science research, data doesn't just inform decisions; it drives them. A single measurement can influence the direction of a study, shape a clinical trial, or determine whether a therapeutic advances. But behind every data point lies a critical question: how much confidence can you place in the assay that produced it?

As research grows more complex and timelines more demanding, that question becomes increasingly important.

From early biomarker discovery to translational and clinical research and biotherapeutic development, immunoassays remain essential for measuring proteins in biological systems. Their value lies in transforming complex biology into actionable insight. But that transformation requires more than sensitivity. It demands quality engineered into every step of the assay.

Where Variability Begins

Biological samples are inherently complex. Serum, plasma, and other matrices contain thousands of components that can interfere with assay performance. Binding proteins, anti-animal antibodies, rheumatoid factors, and subtle shifts in pH or salt concentration can all disrupt antibody interactions and distort results.

These matrix effects are a leading source of variability. Left unaddressed, they can obscure true biological signals, introduce false positives or negatives, and compromise data integrity.

At the same time, research demands are intensifying. Studies now span longer timelines, involve larger datasets, and often require reproducibility across multiple labs and operators. In this environment, it's not enough for an assay to work once: it must perform consistently over time.

Feature continues →

What researchers ultimately need are assays they can trust from the start.

To manage this risk, many researchers build additional validation steps into their workflows, conducting bridging studies or verifying performance with each new reagent lot. While effective, these safeguards come at a cost—consuming time, resources, and momentum.

Building Quality into the Assay

Delivering that confidence requires control at every stage of development and manufacturing.

For 50 years, R&D Systems has built a legacy of scientific excellence in cytokines, proteins, antibodies, and immunoassays—becoming a trusted partner in assay development. That experience is grounded in a simple principle: assay performance begins with reagent quality. Highly characterized antibodies, recombinant proteins, and optimized diluents form the foundation of every platform we deliver.

That same **commitment to quality** extends to how our products are made. Our IVD products are manufactured under FDA Quality System Regulations and in compliance with ISO 13485, while our Research Use Only products are produced under ISO 9001-compliant quality systems, ensuring consistent, reliable performance from development through delivery.

These components are then rigorously tested under real-world conditions to ensure reliable performance across complex sample types, with key parameters such as specificity, recovery, linearity, and precision evaluated to confirm accurate analyte detection.

Specialized diluents further reduce non-specific binding and mitigate matrix effects, helping preserve accuracy even in challenging samples. The objective is not just strong performance in a single experiment, but reproducibility across users, laboratories, and extended studies.

Watch: Learn About Our Quantikine ELISA Kits

A Continuum of Trusted Technologies

This commitment to quality extends across a full portfolio of R&D Systems immunoassay platforms, giving you the flexibility to choose the right approach without sacrificing confidence your data.

Quantikine™ ELISA Kits remain a trusted benchmark for protein quantification, offering ready-to-use kits with proven lot-to-lot consistency. Quantikine QuicKit ELISA Kits accelerate workflows, delivering reliable results in as little as 90 minutes.

For flexible assay development, **DuoSet® systems** provide flexibility when preconfigured kits are not available.

R&D Systems Assays for Luminex® enable multiplex analysis, allowing simultaneous measurement of multiple analytes from minimal sample volume.

For labs prioritizing automation and a simplified workflow, **Simple Plex™ assays on the Ella™** platform eliminate manual steps, reducing variability while delivering highly reproducible, sensitive results.

Across platforms, a shared analytical foundation ensures consistency. R&D Systems Luminex Assays and Simple Plex cartridges are correlated against Quantikine ELISAs, enabling seamless transitions without compromising data continuity.

Immunoassay Product Comparison

	Simple Plex Assays	ELISA Kits	Luminex Assays
Summary	Sensitive 90 minute automated biomarker detection	Researchers most trusted and cited ELISA	High plexing biomarker discovery
Format	Cartridge	96-well plate	Bead
Suggested Application	Single or multiplex	96-well plate	Multiplex detection
Instrument	Ella	Plate reader	Luminex
Sample Volume	2.5-25 µL	50-200 µL	50 µL
Analytes per Sample	Up to 8 analytes	1 analytes	Up to 50 analytes
Menu	350+ analytes across 4 species	1600+ analytes across 15 species	650+ analytes across 5 species

The Confidence Behind Discovery

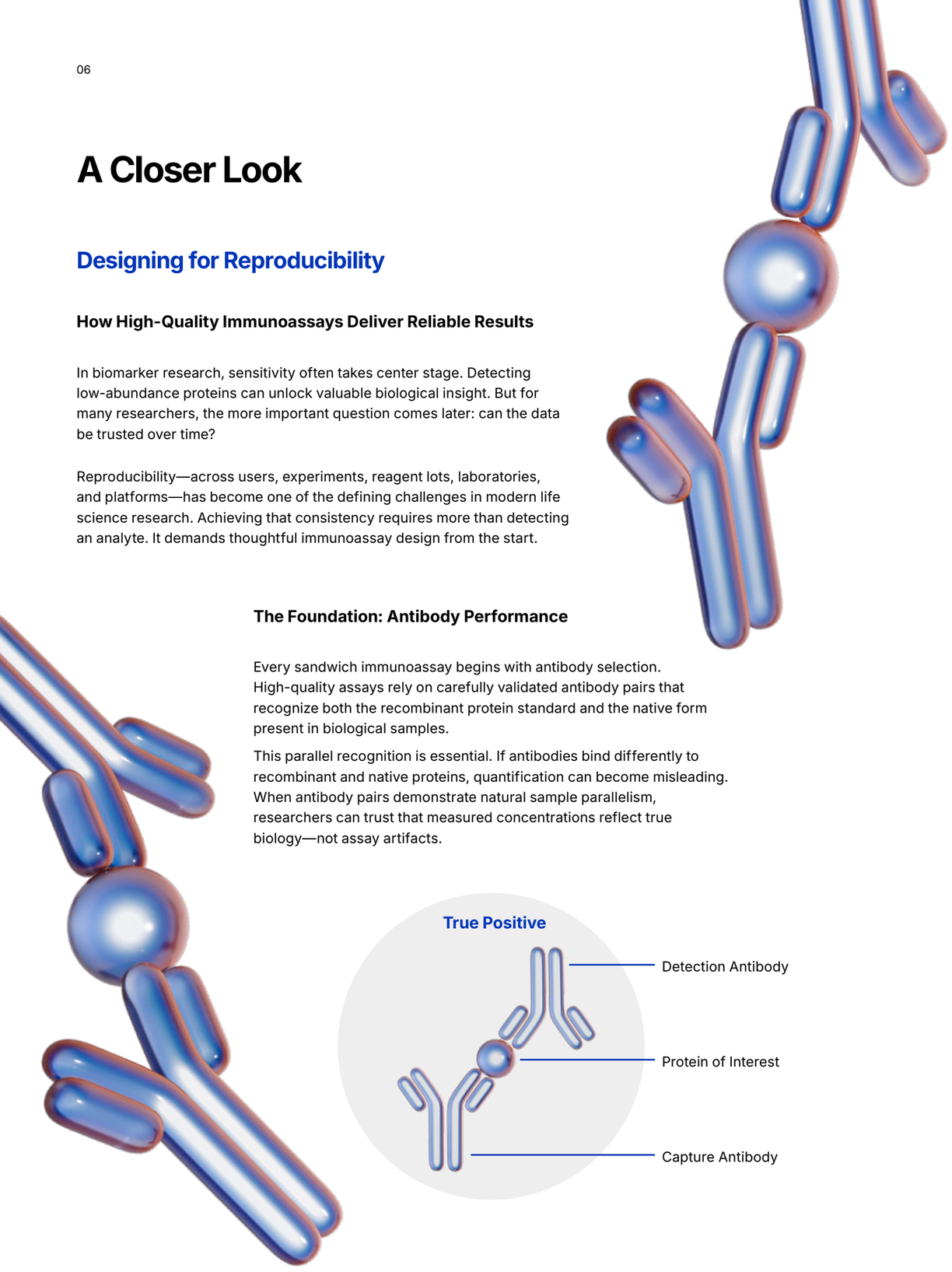
In today's research environment, quality is more than a technical requirement: it's a strategic advantage.

Reliable immunoassays reduce troubleshooting, streamline workflows, and ensure that early data remains comparable as studies evolve. That consistency allows researchers to move forward with confidence, knowing their results are built on a dependable foundation.

With decades of expertise and rigorous quality systems guiding every stage of development, R&D Systems products deliver the reproducibility and reliability researchers depend on.

Because when assay quality is assured, every result carries greater confidence—and every discovery has the potential to go further.

Explore Immunoassay Products, Platforms, and Services / rndsystems.com/immunoassays



A Closer Look

Designing for Reproducibility

How High-Quality Immunoassays Deliver Reliable Results

In biomarker research, sensitivity often takes center stage. Detecting low-abundance proteins can unlock valuable biological insight. But for many researchers, the more important question comes later: can the data be trusted over time?

Reproducibility—across users, experiments, reagent lots, laboratories, and platforms—has become one of the defining challenges in modern life science research. Achieving that consistency requires more than detecting an analyte. It demands thoughtful immunoassay design from the start.

The Foundation: Antibody Performance

Every sandwich immunoassay begins with antibody selection. High-quality assays rely on carefully validated antibody pairs that recognize both the recombinant protein standard and the native form present in biological samples.

This parallel recognition is essential. If antibodies bind differently to recombinant and native proteins, quantification can become misleading. When antibody pairs demonstrate natural sample parallelism, researchers can trust that measured concentrations reflect true biology—not assay artifacts.

Standard Curves That Reflect Biology

Equally important is the design of the standard curve. The assay's dynamic range must align with biologically relevant concentrations.

When properly optimized, assays maintain both sensitivity and accurate quantification across a broad range. Poorly designed curves can compress signals, elevate background noise, or mask meaningful differences between samples.

Consistency from Lot to Lot

Long-term studies often span months—or years—requiring multiple kit lots, reagent batches, or instruments. Without rigorous manufacturing controls, even small variations can introduce unwanted noise.

To prevent this, robust immunoassays anchor each new lot to a consistent calibration framework, ensuring that standard curves, sensitivity, and background remain stable. This consistency allows results generated months apart to be compared with confidence (see Figure 1).

FIGURE 1A

Consistent Control Values in Quantikine ELISAs

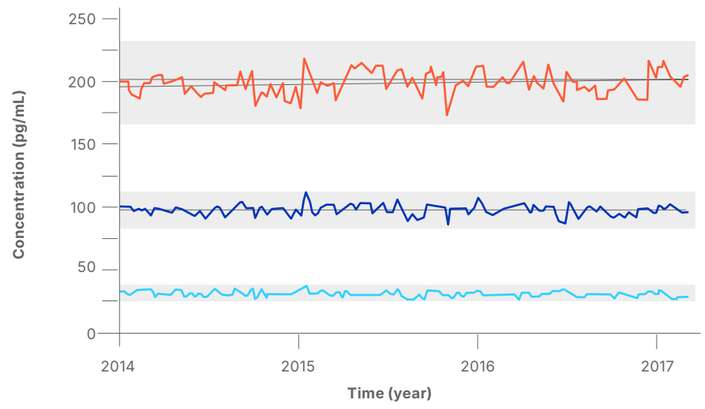


Figure 1A. High (orange line), medium (blue line), and low (light blue line) controls assayed with every manufactured lot of the Human IL-6 Quantikine ELISA kit (**Catalog #D6050**). Controls for the Human IL-6 Quantikine ELISA Kit fall withing acceptable ranges (grey bars) and remain consistent from lot to lot.

FIGURE 1B

Consistent Control Values in Luminex Panel

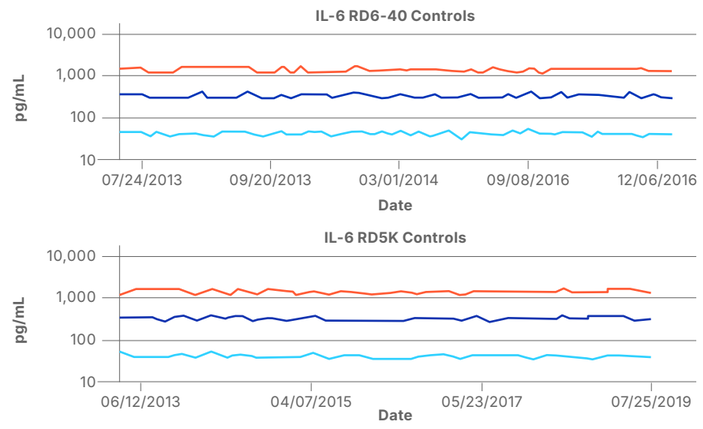


Figure 1B. High (orange line), medium (blue line), and low (light blue line) controls are assayed with every manufactured lot of the Human IL-6 Performance Luminex Assay (**Catalog #LUXLM206**). Controls for the Human IL-6 Luminex Assay remain consistent from lot to lot over the course of 6 years.

Precision Within and Between Experiments

Precision is another key measure of assay reliability. Intra-assay precision reflects agreement between replicates within a single run, while inter-assay precision measures reproducibility across experiments.

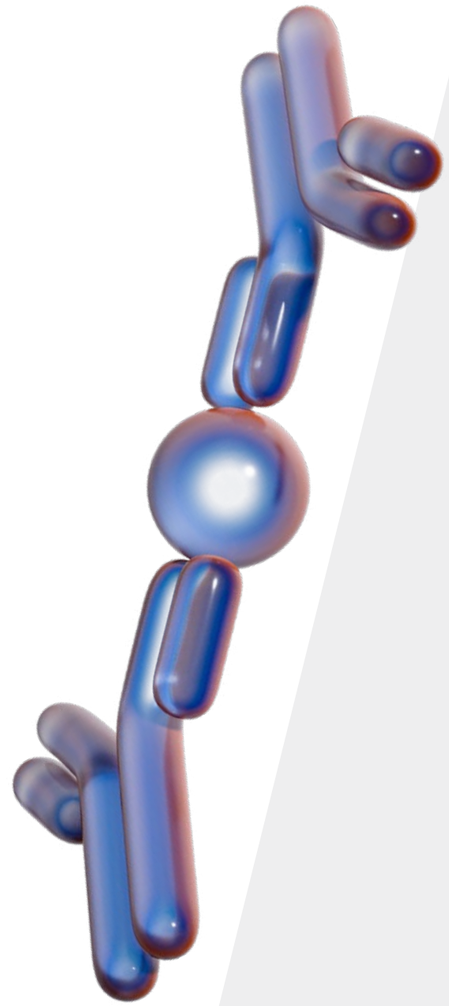
Low coefficients of variation (CVs) ensure that observed differences reflect real biological changes—not analytical variability. This becomes especially critical in clinical biomarker studies, where even small shifts in concentration can carry significant meaning.

Multiple Tools, One Quality Framework

Different research needs call for different immunoassay approaches. Some studies rely on ready-to-use kits for single-analyte detection, while others require customizable systems or multiplex technologies to measure multiple proteins simultaneously. Increasingly, automated platforms are helping reduce manual variability and standardize workflows across labs.

Despite these differences, the most reliable assays share a common foundation: validated antibodies, optimized assay ranges, strict manufacturing controls, and rigorous performance testing.

When these elements are built into the assay design, researchers gain more than sensitivity alone. They gain the ability to generate consistent, trustworthy data across experiments, laboratories, and time—the true cornerstone of high-quality immunoassay research.



Learn More

Scan the QR code or visit
rndsystems.com/quality

Did You Know?

Understanding Matrix Effects

The Hidden Variable in Immunoassays

Even the most sensitive immunoassay can be influenced by something often overlooked: the sample itself.

Biological matrices like serum and plasma contain thousands of proteins, antibodies, and other molecules that can interfere with antibody–antigen interactions. These matrix effects can distort assay signals, leading to inaccurate quantification, reduced recovery, or inconsistent results across samples.

Common sources of interference include binding proteins that mask analytes, rheumatoid factors and anti-animal antibodies that create false signals, and high-abundance proteins or shifts in pH and ionic strength that alter assay behavior. The impact can range from suppressed signal to elevated background noise—both of which compromise data integrity.

Minimizing these effects starts with thoughtful assay design. Optimized diluents, carefully selected antibody pairs, and rigorous performance testing all help reduce non-specific interactions and improve accuracy in complex samples. In the lab, consistency matters just as much. Using recommended diluents, verifying dilution linearity, and standardizing handling practices all contribute to more reliable results.

Because matrix effects are so central to assay performance, they're also a key consideration during antibody development and validation. Antibodies must be evaluated not just for sensitivity, but for how they behave in real biological contexts. That includes assessing cross-reactivity against closely related molecules and, where relevant, confirming functional performance through assays such as blocking, neutralization, or receptor activation. Approaches like these help ensure that reagents perform as expected when moved from controlled conditions into complex sample matrices.

Matrix effects can't be eliminated—but they can be controlled. And when they are, you gain something critical: confidence that your data truly reflects the underlying biology.

Watch: Stringent Antibody Validation Helps Ensure Optimum Performance

Learn More / rndsystems.com/products/antibodies/antibody-validation

Platform Spotlight

From Manual Assays to Automation

How Simple Plex Reduces Immunoassay Variability

Even the most carefully designed immunoassays can be undermined by variability introduced during manual execution. Small differences in technique, timing, and handling may seem insignificant—but over time, they can impact performance in ways that only become visible once variability appears in the data.

As research becomes increasingly data-driven, controlling these hidden variables is no longer optional—it's essential.

The Hidden Variables in Manual Workflows

Traditional ELISA workflows rely on a series of precise, manual steps: pipetting, incubation, washing, and detection. Each introduces an opportunity for subtle variation, even in experienced hands.

Individually, these differences may be minor. Collectively, they can drive higher coefficients of variation (CVs) within and between runs—complicating data interpretation, particularly in longitudinal studies or multi-site research where consistency is critical.

Automation as a Quality Strategy

Automation fundamentally changes this equation.

Simple Plex Assays on the fully automated Ella platform eliminate the variability associated with manual workflows. Once samples and reagents are loaded, the system executes the entire assay—from capture through quantitation—without user intervention.

By removing pipetting inconsistencies, wash variability, and timing differences, Ella standardizes every step of the process. Each sample is run under identical conditions, delivering consistent, reproducible results with minimal hands-on time.

Delivering Consistency Across Labs

Standardization doesn't just improve results within a single lab—it extends across users and sites.

Simple Plex Assays routinely achieve single-digit CVs, even across multiple operators and laboratories. This level of reproducibility is critical for studies requiring reliable biomarker measurements over time or across locations.

Equally important, Simple Plex Assays are correlated to Quantikine ELISAs—long regarded as a gold standard—enabling a seamless transition from manual to automated workflows without compromising data continuity.

Stringent lot-to-lot quality control further ensures consistent performance, supporting confidence in longitudinal sample analysis.

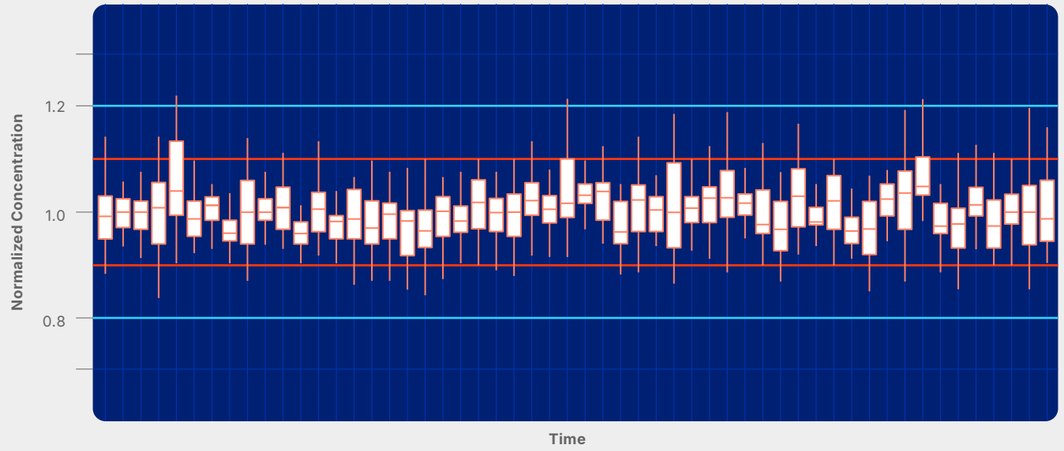
A New Standard for Immunoassay Consistency

As research grows in scale and complexity, the need for standardized, reproducible tools continues to rise. Automation meets this need by removing variability at its source. With Simple Plex Assays, researchers gain more than efficiency—they gain confidence in their data.

When variability is controlled, the focus shifts where it belongs: on the biology behind the results.

FIGURE 2

Natural Matrix Controls



Stringent QC for each lot of Simple Plex cartridges creates repeatable results for longitudinal sample testing.

Featured Product

Multiplexing Without the Barrier

What the Luminex MAGPIX System Means for Your Lab

As biomarker research grows more complex, many labs face the same challenge: generating deeper biological insight without increasing sample demands, workflow burden, or instrument complexity.

That's where multiplexing changes the equation.

The **Luminex® MAGPIX® system** brings proven Luminex® xMAP® technology into a compact, affordable platform that helps you move beyond single-analyte workflows. By measuring up to 50 protein targets in a single sample, MAGPIX allows you to generate broader biological insight while conserving sample volume, saving valuable bench space, and minimizing hands-on time compared to running multiple ELISAs.

For applications like cytokine profiling, inflammatory marker analysis, cell therapy characterization, and translational research, that means fewer individual assays and more meaningful data from every run.

MAGPIX is also designed for ease of adoption. Unlike traditional flow cytometry-based multiplex systems, it uses compact CMOS imaging technology with simplified startup, minimal maintenance, and an ELISA-like workflow that makes transitioning to multiplexing more approachable.

The system supports a broad menu of validated R&D Systems analytes for Luminex assays, including customizable discovery panels with more than 350+ analytes—giving you the flexibility to build panels around your biology, not the limitations of the assay.

For many labs, the practical benefits matter just as much: smaller footprint, low sample input requirements, affordability, and the ability to process a full 96-well plate in about an hour.

As research increasingly depends on multi-dimensional data, multiplexing is becoming essential for understanding complex biology more completely and efficiently. MAGPIX helps make that capability more accessible.

Learn More About the MAGPIX System

Scan the QR code or visit
rndsystems.com/magpix

Assays in Action

Predicting Autoimmune Flare Before It Happens

What if disease flare could be detected before symptoms ever appear?

At the Oklahoma Medical Research Foundation (OMRF), Dr. Melissa Munroe and her team are working to do just that: profiling immune activity in patients with systemic lupus erythematosus (SLE) to uncover early signals of disease progression.

Lupus is notoriously unpredictable, with stable periods giving way to a sudden flare. Traditional biomarkers, however, often miss the earliest immune changes. Using a broader approach, Munroe's team identified a clear pattern: weeks before flare, pro-inflammatory signals rise as regulatory pathways decline, creating a predictive signature no single marker could capture.

To detect these subtle shifts, the team combined large-scale Luminex multiplex profiling with high-sensitivity validation with Simple Plex assays, enabling simultaneous measurement of dozens of immune mediators, including low-abundance targets like interferons and interleukins, from limited sample volumes. Automated workflows further ensured consistent, reproducible results across studies.

By pairing breadth with sensitivity, the team generated deeper insight from every sample—accelerating the identification of patterns linked to disease flare.

The impact: earlier detection could enable clinicians to intervene sooner, personalize treatment, and ultimately improve outcomes for patients living with lupus.

"The assays gave us a level of accuracy and reproducibility we hadn't seen with other platforms

— **Dr. Melissa Munroe, M.D., Ph.D.**
Research Associate, Oklahoma Medical Research Foundation (OMRF)

Read the Full Case Study

Scan the QR code or visit
rndsystems.com/immune-response

Perspective

Inside Immunoassay Quality

Q&A with Mary Ann Williams, VP of Quality and Regulatory Affairs at Bio-Techne

Behind every reliable immunoassay is a foundation of scientific rigor, thoughtful design, and unwavering attention to quality. In this exclusive Q&A, Mary Anne Williams, Vice President of Quality and Regulatory Affairs, discusses the critical factors that influence assay performance, the importance of reproducibility, and how emerging technologies are shaping the future of research. Her insights offer valuable guidance for researchers seeking greater confidence in their data.

When researchers talk about "high-quality immunoassays," what do you think they're often missing or oversimplifying?

Generally speaking, unless one has experience in the immunoassay business, it is hard to appreciate the complexity involved in bringing a "high-quality immunoassay" to the research market. A high-quality immunoassay should be robust and fit-for-purpose.

Robustness ensures consistent performance across real-world conditions – different sample types, different operators, and different laboratories, and over time. This level of performance is achieved through qualifying both the raw materials and our suppliers, validation of our manufacturing processes, and setting appropriate product release criteria.

How early in assay development does "quality" actually come into play?

Quality comes into play at the very start of our design process. Defining user needs, establishing fit-for-purpose parameters, assessment of risk, and selection of the antibodies and antigen design are activities that occur at the early stages of the project.

Risk management continues to be an integral part of the development process, with reviews and assessment updates occurring throughout the development process. Lessons learned and expertise-gained from Bio-Techne's five-decades of experience provide tremendous insights into both performance and risk and are a valuable cornerstone of our new assay realization process. This mindset fundamentally shapes how we design and validate every assay with the primary goal of delivering a product that will work consistently across hundreds of runs, multiple lots and diverse biological samples.

What are some of the most critical—but less visible—factors that influence assay performance?

That's a great question. A few factors come to mind. How well antibody pairs recognize natural proteins compared to recombinant standards? How is the standard curve constructed and validated? And then there's matrix behavior—how real biological samples interact with the assay. These factors are not always visible in a datasheet, but they have a significant impact on whether results truly reflect biology or are influenced by assay conditions.

Reproducibility is a major concern in life science research. How do you approach it from a quality and manufacturing perspective?

Reproducibility is the outcome of robust design control processes, a critical aspect of Bio-Techne's quality system. From our perspective, achieving reproducibility comes down to minimizing variability at every step—raw materials, manufacturing processes, calibration standards, and validation criteria. We focus on lot-to-lot consistency testing to ensure that a researcher using a kit today will get comparable results with a kit produced months later. The successful outcome of long-term or multi-site studies is built upon that continuity.

How do you balance the need for flexibility in research with the need for standardized, high-quality assays?

That's where a well-rounded portfolio becomes important. Some researchers need fully validated, ready-to-use assays that minimize variability and save time. Others are looking for the flexibility to build or adapt assays for their own specific applications. We strive to support both approaches while maintaining the same underlying quality standards—whether that's through complete kits, development systems, multiplex formats, or automated platforms.

Where does automation fit into the broader conversation around quality?

Automation plays a key role in reducing one of the biggest sources of variability: human execution. Pipetting, washing, and timing are all manual steps that can contribute to inconsistencies, even in well-run labs. By standardizing those steps, automated platforms help ensure that results are reproducible across users and locations. It is important to note that automation doesn't replace assay quality: it amplifies it. The underlying assay still needs to be well-designed and well-validated.

How do you ensure consistency across different platforms and technologies?

Consistency across platforms starts with a shared foundation—validated antibodies, well-characterized standards, and rigorous performance testing. When assays are developed with those principles in mind, it facilitates the correlation of results across formats, from traditional ELISA, multiplex assays, to automated systems. Cross-platform continuity gives researchers the flexibility to scale or adapt their workflows with confidence.

What role does long-term data confidence play in how you define quality?

From my perspective, a high-quality immunoassay is essential to having confidence in your data. This applies regardless of whether the data was generated across a short-term or a long-term. Researchers make data-driven decisions on a daily basis. In the case of an extended study, a consistent data set is essential as it enables the researcher to draw meaningful study conclusions.

Quality, from our perspective, enables researchers to compare results across time with confidence—knowing that any differences they see are biological rather than technical.

Looking ahead, how do you see expectations around immunoassay quality evolving?

Immunoassays have proven to be flexible and adaptable over the past several decades. As a developer and manufacturer of these products, it is our responsibility to keep pace with the increasing expectations of our customers. Researchers are working with more complex samples, lower analyte concentrations, and more demanding study designs. At the same time, there's a growing emphasis on reproducibility and data transparency. I think we'll continue to see a shift toward more standardized, highly controlled assay systems, along with greater integration of automation and data validation. Ultimately, the goal remains the same: to generate data that researchers—and the broader scientific community—can trust.

If you could give researchers one piece of advice when selecting an immunoassay, what would it be?

Look beyond a single performance metric and keep "fit-for-purpose" front of mind. Consider how the assay was designed, how does it perform across real sample types, and how consistent will it be over time. The most valuable assays are the assays that you can rely on throughout the entire lifecycle of your research.

New Products

More Targets, Deeper Insight

Expanded multiplexing for a more complete view of biology

Understanding complex biology—especially in cell therapy—requires more than single-analyte answers. Whether characterizing immune activation or confirming potency prior to release, meaningful insight depends on seeing how multiple pathways interact.

That's where multiplexing becomes essential—capturing a broader, more connected view of biology from every sample.

The latest expansion of the R&D Systems Human Luminex Discovery Assay builds on this approach, adding 17 new analytes—including CD21/CR2, CRHBP, and Intelectin-1/Omentin-1—targets uniquely available from R&D Systems. Combined with a menu of more than 350 analytes, this expanded coverage enables highly customizable panels that assess activation, effector function, and regulatory pathways in parallel.

The impact is twofold: deeper biological insight and greater efficiency. By measuring multiple targets simultaneously, you conserve valuable sample while generating richer, more informative datasets.

From early discovery through translational research and QC testing, flexible panel design and proven reproducibility on Luminex platforms ensure consistent, high-quality results—so you can move forward with confidence that your data reflects the full complexity of the system you're studying.

Explore the Expanded Menu: Human Luminex Discovery Assay / rndsystems.com/products/human-luminex-discovery-assay_lxsahm

Latest Assays

ELISA Kits	Human IL-10 QuicKit ELISA	QK1064
	QuicKit Immunoassay Control for Human IL-10	QC319
Luminex Panels	Human Luminex Discovery Assays	LXSAHM

NEW Analytes

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

Simple Plex Assays	72x1 Cartridge Ultra-Sensitive NF-L	ST01B-PS-015538
	72x1 Cartridge Ultra-Sensitive GFAP	ST01B-PS-015539
	72x1 Cartridge Ultra-Sensitive pTau217	ST01B-PS-015536
	32x2 Panel Ultra-Sensitive NFL/GFAP	ST01C-PS-015256
	32x2 Ultra-Sensitive pTau217/Ab1-42	ST01C-PS-015464

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.

Submit Your Story Today

Scan the QR code or visit
rndsystems.com/immune-response

Upcoming Events

FENS Forum 2026

July 6-10 Barcelona, Spain fensforum.org/satellite-events

AAIC

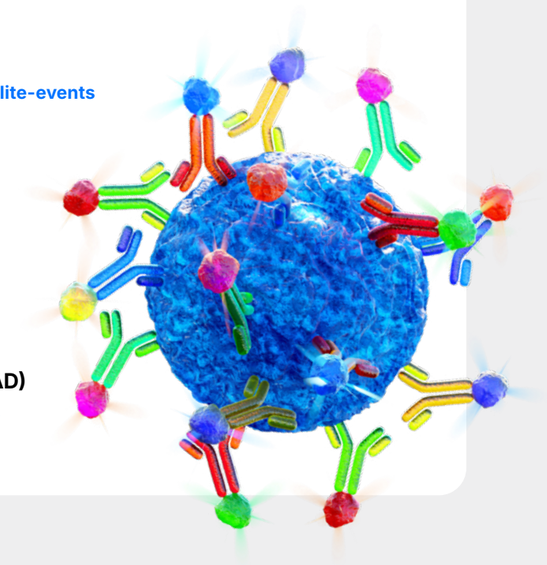
July 12-15 London, UK aaic.alz.org

Society for Neuroscience

Nov. 14-18 Washington, DC sfn.org/meetings

Clinical Trials on Alzheimer's Disease conference (CTAD)

Nov. 16-19 Boston, MA ctad-alzheimer.com



Analyte Menu

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

Full Simple Plex Menu / rndsystems.com/simpleplexmenu

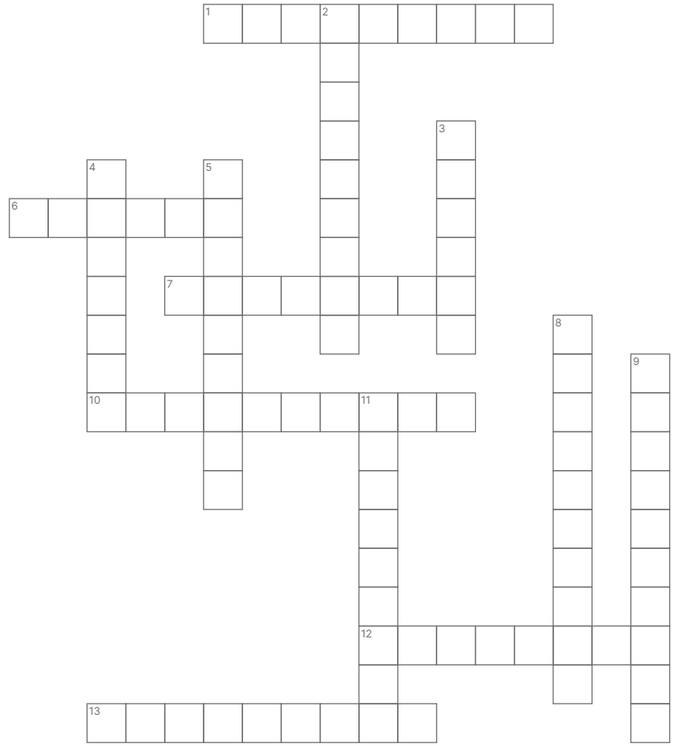
Full ELISA Menu / rndsystems.com/elisa

Full Luminex Menu / rndsystems.com/luminex

Contact an Immunoassay Specialist / rndsystems.com/support/contact-us/sales-support

Crossword

Lab Break: Test Your Immune System Fundamentals



Across

1. Filters bacteria and other agents of disease from lymph
6. The body's immunity that a person is born with to defend against infection
7. The immunity that is tailored to particular pathogens that enter the body
10. Phagocytic cell that accounts for two-thirds of white blood cells
12. The body's ability to resist and fight infections
13. Substances released by white blood cells to strengthen immune response.

Down

2. White blood cell that engulfs and destroys foreign agents
3. Lymphatic system's largest organ
4. Molecule of particle that the immune system recognizes as non-self
5. Cell that alerts the adaptive immune system when antigens are detected
8. White blood cell that targets parasites, such as worms
9. White blood cell that plays a central role in adaptive immunity
11. Chemical released by mast cells which causes inflammation

Crossword Answers
Across: 1. lymphnode 6. innate 7. adaptive 10. neutrophil 12. immunity 13. cytokines
Down: 2. phagocyte 3. spleen 4. antigen 5. dendritic 8. eosinophil 9. lymphocyte 11. histamine

R&D systems by bio-techne

10928.0.0426