

PLATFORM COMPARISONS GUIDE

**How to Comprehensively Evaluate
Your Bioanalytical Technology Options**

NEW EXPANDED EDITION | JULY 2016

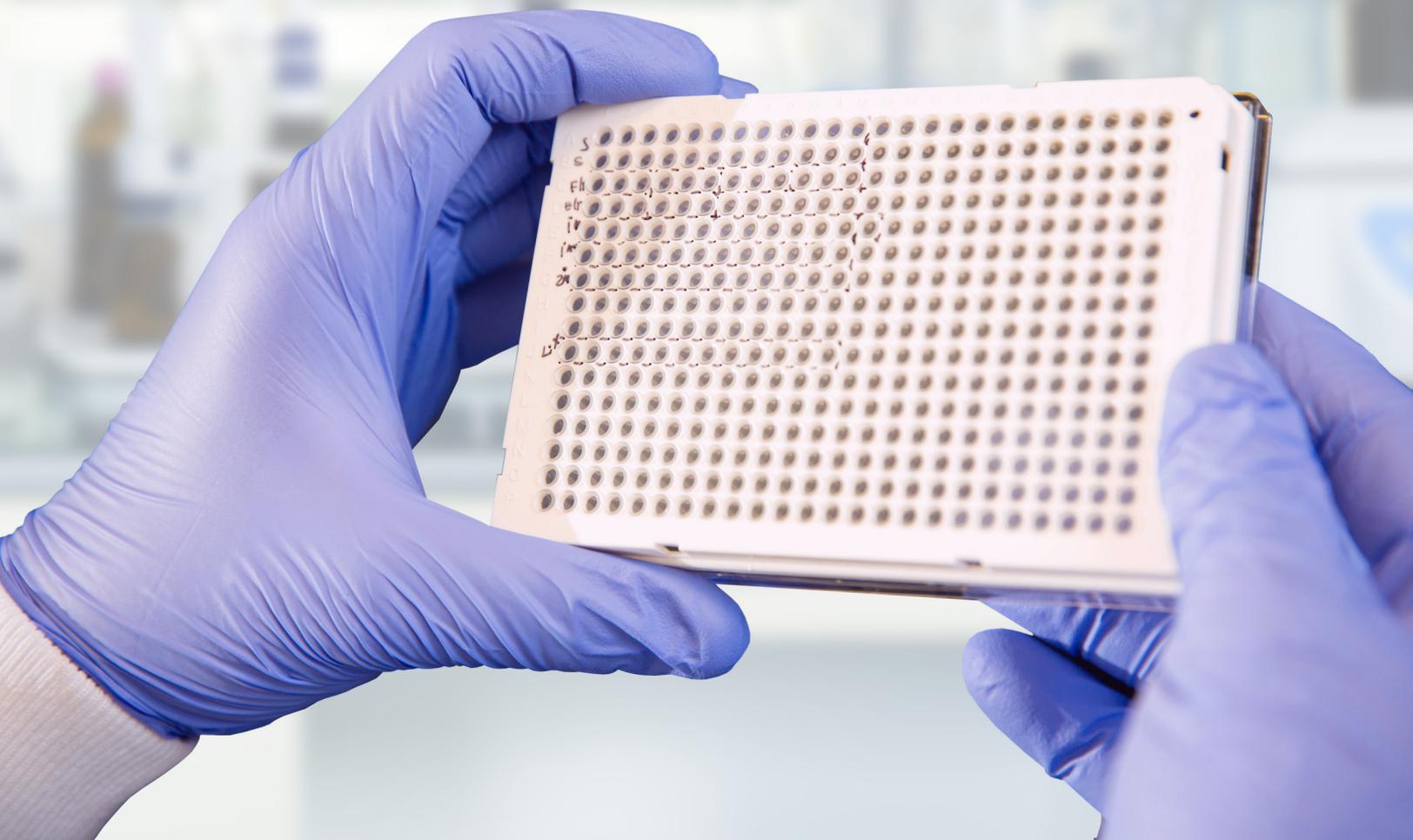


TABLE OF CONTENTS

Introduction	3
Platform Selection Considerations	4
Assay Demands	5
Sample Volumes	5
Level of Regulatory Compliance	6
Experience with Technology	6
Reagent Availability	6
Platform Comparisons: A Closer Look	7
ELISA	7
MSD-ECL	8
Gyros	9
ProteinSimple	10
Flow Cytometry	11
DELFI A	12
LI-COR	13
Biacore	14
ImmunoCAP	15
ELISPOT	16
LightCycler	17
Randox	18
Luminex	19
Platform Evaluation Worksheet	20
Conclusion	21
About BioAgilytix	22

INTRODUCTION

In the competitive realm of biologic development, technology can create an important advantage. Innovative instrumentation enables more accurate and efficient assay analysis by yielding benefits such as greater throughput and better reproducibility. For these reasons, the platform you choose for your study could have a significant impact on both the time to results and success of your project.

It is critical to select technology that meets your distinct assay sensitivity and performance requirements. In many cases, the platform used is just as important to results as the skill of the scientific team running the analysis. But how do you determine the right platform for your project among the ever-growing options now available?

There are a number of factors that impact platform selection, from precision needs to implementation costs. It requires careful evaluation of your requirements, compared against the capabilities of each platform available, to make the most appropriate choice.

Your organization may already have instrumentation in-house, but you should also look beyond your internal options if they cannot fully satisfy your project requirements. CROs that specialize in large molecule bioanalysis often possess broader platform suites, and are more likely to be actively adding new technologies that create greater flexibility to support their customers' work. Through a CRO relationship, you can more easily access advanced instrumentation that is optimal for your needs.

This Platform Comparisons Guide breaks down the key selection criteria to be considered when exploring bioanalytical technology options. It also takes a closer look at some of the most popular and innovative platforms used in large molecule bioanalysis today, giving you the insight to effectively compare their capabilities, features, and benefits relative to your assay needs.

This **Platform Comparisons Guide**

breaks down the key selection criteria to be considered when exploring best-fit bioanalytical technology options, including:

- ELISA
 - MSD-ECL
 - Gyros
 - ProteinSimple
 - Flow Cytometry
 - DELFIA
 - LI-COR
 - Biacore
 - ImmunoCAP
 - ELISPOT
 - LightCycler
 - Randox
 - Luminex
-

PLATFORM SELECTION CONSIDERATIONS

The first step in successful platform selection is to determine the parameters within which your assay requirements fall. Some factors are simple to define: is the study regulated or non-regulated? Others need to be weighed carefully against project characteristics: are you likely to run into matrix effects? What is an acceptable sensitivity range? Are any decision parameters worth higher costs?

These questions are critical to answer upfront if you want to ensure a smooth bioanalytical process with the results that best meet your needs. Perhaps you don't need extreme sensitivity, or your sample sizes are not restricted. In those cases, a traditional platform would likely be the most cost-effective choice. It is when analysis calls for high degrees of sensitivity or throughput that you will want to look to the more innovative platform options now on the market.

Whether you are running the analysis internally or working with a CRO partner, these are some of the key parameters to consider when selecting the right platform for the job.

- | | |
|---|--|
|  Sensitivity |  Total Assay Time |
|  Precision |  Multiplexing |
|  Dynamic Range |  Throughput |
|  Matrix Interference |  Adaptability to Automation |
|  Regulatory Compliance Level |  Ease and Cost of Implementation |
|  Robustness and Ruggedness |  Sample Size |

Other questions need to be weighed carefully against project characteristics:

- Are we likely to run into matrix effects?
- What is an acceptable dynamic range?
- Is greater precision worth higher cost?

CONSIDER:

Assay Demands

Ligand binding assays (LBAs) are used to measure biologic therapeutic levels, with the most common LBA method being ELISA. Its cost-effective plates and associated reagent supplies have made it a popular platform choice since the early 1970s.¹ However, when compared to newer options like Meso Scale Discovery (MSD) or Gyrolab, you can gain significant increases over ELISA's sensitivity and dynamic range.

ELISA may be the right choice for less complex assay needs, but when multiplexing, higher sensitivity, or wider dynamic range are required, you should look to more advanced platforms that are better able to meet those requirements. Make sure you lay out all the demands for your large molecule study—both current and anticipated as it progresses through development phases—to ensure the chosen platform can accommodate those needs.

Make sure you lay out all the demands for your large molecule study—**both current and anticipated as it progresses through development phases**—to ensure the chosen platform can accommodate those needs.

CONSIDER:

Sample Volumes

There are platforms specifically designed for limited sample volumes. Your specific sample profile should be carefully evaluated by either your internal team or CRO partner, with focus on conserving precious volume as much as possible.

Oftentimes the platforms that enable higher throughput, like the Gyrolab for immunoassays, will also yield faster sample analysis turnaround time—delivering high-quality results quickly to further compress your development timeline.

Your specific sample profile should be carefully evaluated with focus on conserving precious volume as much as possible.

CONSIDER:

The Level of Regulatory Compliance

You may not need to follow GLP or GCP standards in the discovery phase of your bioanalytical project, but as your program advances into pre-clinical testing and beyond, you will need to make sure your platform supports necessary compliance requirements. An ideal platform is one that is applicable through all stages of the drug development process, as it mitigates the added costs and risk of switching platforms mid-study.

Data integrity is of critical concern in regulated studies, so you must also make sure the platform upholds the analytical performance needed to manage and meet compliance requirements. While analytical requirements may differ through each development phase, the platform must produce the needed data to support both business-critical decision making and quality assurance demands.

An ideal platform is one that is **applicable through all stages of the drug development process.**

CONSIDER:

The Scientists' Experience with the Technology

In the end, your platform will only be as effective as the team using it. Your internal scientists are likely quite familiar with the existing platforms in your own lab, but if your project requires you to contract the services of a CRO, you will need to assess their scientists' capabilities and track record working with the advanced technology you plan to employ.

Ideally your CRO partner will have the expertise and skill to tailor their methods to meet even your most rigorous assay performance demands.

In the end, your platform will **only be as effective as the team using it.**

CONSIDER:

Reagent Availability

In emerging and exploratory biomarker development, there are times when critical reagents are not well characterized. In those situations, there are platforms designed specifically for assays with only one good antibody available, and assays requiring separation based on either size or charge prior to analysis.

The extent to which **critical reagents are characterized** may impact your platform selection.

ELISA

Enzyme-Linked Immunosorbent Assays

ELISAs are designed for detecting and quantifying substances such as peptides, proteins, antibodies and hormones, and are typically performed on an 96-well plate. Detection is done by assessing the conjugated enzyme activity via incubation with a substrate to produce a measurable signal.

HOW IT WORKS

To perform an ELISA, there must be at least one antibody with specificity for a particular antigen. The sample with an unknown amount of antigen is immobilized, with the detection antibody then added. The plate will passively bind antibodies and proteins, and is then developed by adding an enzymatic substrate to produce a visible signal that indicates the quantity of antigen is captured on a plate and followed by incubation with the detection antibody.

The binding and immobilization of reagents makes it easy to separate bound from nonbound material during the assay, and wash away nonspecifically bound materials to measure specific analytes.

WHERE ELISA 'WINS'

ELISA is the most common method for LBAs, and has been in use since the 1970s. It is optimal when you need a fast, reliable, and cost-effective platform for analyte quantification of specific assays.

Advantages

- High Precision
- High Throughput
- Fluorescence and Luminescence
- Does Not Require Radioactive Substances
- Proven Method
- Broad Applicability
- Easy to Design & Perform
- Typically Cost-Effective

Disdvantages

- Newer Platforms Offer Higher Sensitivity and Throughput
- Small Dynamic Range
- Not Capable of Multiplexing

Top Applications

- Biomarkers
- Immunogenicity
- Pharmacokinetics
- Cell-Based Assays

MSD-ECL

Meso Scale Discovery® Electrochemiluminescence

Although similar to a traditional ELISA, MSD-ECL uses non-radioactive electrochemiluminescent labels for ultra-sensitive detection, yielding higher sensitivity and broader dynamic range, all at lower sample volumes.

HOW IT WORKS

Electrochemiluminescence detection uses labels that emit light when electrochemically stimulated. The detection process is initiated at electrodes located in the bottom of the MSD's microplates, and only labels near the electrode are excited and detected. The system employs buffers with high concentrations of Tripropylamine as a catalyst for a dual redox reaction with Ruthenium, emitting light at 620 nm.

Reliability is improved because few compounds interfere with these types of labels. MSD also uses multiple excitation cycles of each label to amplify the signal, enhancing light levels for improved sensitivity.

WHERE MSD-ECL 'WINS'

MSD-ECL provides a strong alternative to conventional colorimetric methods like ELISA, when high sensitivity and multiplexing are critical. It is also optimal for complex matrices as it typically yields low interference from components like serum or plasma.

Advantages

- Very High Sensitivity
- Broad Dynamic Range
- High Precision
- Robust and Rugged
- Reduced Sample Volume
- High Throughput
- Reduced Matrix Effects
- Multiplexing
- High Tolerance to Circulating Antigen
- Does Not Require Radioactive Substances

Disdvantages

- All Reagents and Instrumentation Supplied by a Single Vendor
- High Cost of Consumables
- Lot to Lot Variability

Top Applications

- Biomarkers
- Immunogenicity
- Pharmacokinetics
- Cell-Based Assays
- Lot Release Testing

Gyros

Gyrolab™ xP

This cutting-edge platform analyzes immunoassays on a nano-liter scale, automating finely controlled immunoassays in identical microfluidic channels using highly sensitive, laser-induced fluorescence (LIF) detection.

HOW IT WORKS

Gyros automates analysis of large numbers of samples, processing up to 5 Gyrolab CDs in a series. The CDs are spun at controlled speeds to ensure optimal binding and uniform conditions for all assays.

Through automation, Gyros minimizes variability that may otherwise occur during manual sample and reagent loading. Because all reactions happen as assay components “flow” over the microstructure, non-specific matrix interference is reduced and sample volumes are dramatically reduced. It also generates same-day results to support rapid decision making.

WHERE GYROS ‘WINS’

Gyros is likely to be most valuable when used in larger studies that use small sample volumes but require frequent sampling. By greatly reducing sample and reagent consumption, it removes time- and cost-consuming roadblocks faced with limited sample availability in more traditional methods.

Advantages

- Automates Assay of Samples in Parallel
- Greatly Reduced Sample Volume
- Reduced Reagent Consumption
- High Throughput
- Increased Matrix Tolerance
- Improved Precision and Accuracy
- Wide Dynamic Range
- Generates Same-Day Results
- High Sensitivity and Precision
- Robust and Rugged
- Gyrolab Viewer Provides Detailed Binding Profiles

Disadvantages

- Requires Regular Technical Upkeep
- Not Cost-Effective at Smaller Sample Sizes
- Costly Consumables
- Single Vendor Provider

Top Applications

- Biomarkers
- Pharmacokinetics
- Lot Release Testing

ProteinSimple

Simple Western Peggy Sue™

ProteinSimple is an automated capillary immunoblotting system that enables the development of assays when there is only one antibody available, and/or when separation based on size and charge is required prior to analysis.

HOW IT WORKS

Simple Western assays combine capillary electrophoresis, a traditional separation technique, with an immunoassay, a well-known detection technique. This allows quantitative Westerns to be performed with sensitivity and reproducibility unmatched by traditional Western blot methods.

ProteinSimple's Peggy Sue platform will process up to 96 samples at a time, using as little as 0.05 µg/mL of protein. Full automation mitigates manual variability, and cuts out gel separation or transfer of proteins to yield immediate quantitative results.

WHERE PROTEINSIMPLE 'WINS'

ProteinSimple has essentially reinvented Westerns, removing the issues and frustrations with reproducibility, sensitivity, quantifiability, and speed seen in traditional methods. If these parameters are critical to your project, ProteinSimple may be the right choice.

Advantages

- Automates Western Blot Analysis with Improved Sensitivity Over Traditional Methods
- Separation Based On Size and/or Charge
- Reduced Sample Volume
- High Sensitivity
- High Precision
- Linear Dynamic Range
- Quantitative and Qualitative Assays
- Very High Reproducibility
- High Throughput
- Multiplexing

Disadvantages

- Newer Technology, Lesser Known
- Costly Compared to Traditional Western Blot
- Costly Consumables
- Limitations for Regulatory Compliance
- Single Vendor Provider

Top Applications

- Biomarkers
- Wide Variety of Matrices

Flow Cytometry

Cytek DXP8 FACSCalibur™

Flow cytometry—commonly referred to as FACS analysis—is a laser-based technology used for cell detection and quantification of biomarkers on individual cells. Using specific probes, data on desired biomarkers can be obtained from target cells in complex mixtures such as peripheral blood or bone marrow.

HOW IT WORKS

Flow cytometers utilize a sophisticated array of lasers, optics, fluidics and electronic detectors to measure light scatter and/or fluorescence emission from cells, running them one at a time through a laser to quantitate physical properties of the cells, including cell size, granularity, and the amounts of target proteins.

As the cells pass through a laser, they absorb the laser's light and then emit a specific color signal based on targeted fluorochromes, to determine the amount of each type of cell in the sample or the amount of target expressed by the individual cells.

WHERE FLOW CYTOMETRY 'WINS'

Flow cytometry is a method that proves very accurate and effective when used to identify and measure cellular biomarkers in complex subpopulations.

Advantages

- High Accuracy
- Subpopulation Analysis
- Strong Reproducibility
- Suited for Automation
- Quantitative Analysis of Cellular Biomarkers
- Single and Multicolor
- Drug Targeting, Potency and Molecular Internalization
- Biomarker Expression Monitoring

Disdvantages

- Slow Processing Speed for Larger Volumes
- Cell/Sample Viability May Limit Some Measurements
- Sample Stability is Key to Success

Top Applications

- Biomarkers
- Immunogenicity
- Cell-Based Assays
- Immunophenotyping

DELFLIA

Dissociation-Enhanced Lanthanide Fluorescent Immunoassay

An alternative to the traditional ELISA platform, DELFLIA utilizes the unique chemical properties of lanthanide chelates in concert with time-resolved fluorescence (TRF) detection to create an assay that offers high sensitivity, wide dynamic range, superior stability, and excellent flexibility.

HOW IT WORKS

In DELFLIA, the use of an enzyme is not necessary to generate a signal. It instead uses a fluorescent DELFLIA chelate as the readout. A DELFLIA assay is virtually identical to that of a standard sandwich ELISA, with the analyte first captured on the coated microplate, and the detection antibody added to complete the sandwich. But unlike ELISA, a lanthanide chelate-labeled detection antibody is used, and an enhancement step unique to DELFLIA releases the lanthanide from the antibody complex, producing a new, highly fluorescent lanthanide chelate contained within a protective micelle.

This enables highly sensitive detection of low concentration targets and rare biological events, with lower sample and antibody volume requirements.

WHERE DELFLIA 'WINS'

DELFLIA is ideal for complex sample matrices and is particularly well suited for TRF, kinase, and immunodetection assays, as well as discovery work when the assay must be highly sensitive, specific, reliable, and reproducible.

Advantages

- Very High Sensitivity
- Broad Dynamic Range
- Strong Assay Stability
- Low Fluorescent Background
- Enhanced Flexibility
- High Precision
- Robust and Rugged

Disadvantages

- No Multiplexing

Top Applications

- Biomarkers
- Immunogenicity
- Pharmacokinetics
- Cell-Based Assays
- TRF Assays
- Kinase Assays

LI-COR

LI-COR Odyssey

LI-COR is a laser-based platform that delivers quantitative accuracy for target protein detection by using an infrared technology to match or exceed chemiluminescent detection sensitivity for quantitative Western Blots.

HOW IT WORKS

LI-COR uses infrared detection with corresponding infrared fluorescent-labeled secondary antibodies to provide quantitative analysis and a wide linear dynamic range that is not available with traditional chemiluminescent methods.

LI-COR enables the detection of two targets simultaneously on the same membrane, which greatly increases accuracy of quantification and provides for more robust comparison. It yields very low background fluorescence, which enables detection of low-picogram targets with NIR fluorescence, as well as low abundance proteins at endogenous levels. Adjustable scanning depth allows work with cell-based assays on in-gel detection.

WHERE LI-COR 'WINS'

LI-COR's near-infrared fluorescent detection has broad applicability for quantitative Western blots, protein gel imaging, and in-cell Westerns, offering superior sensitivity compared to traditional methods.

Advantages

- Quantitative Western Blots
- Wide Linear Range
- High Sensitivity
- Broad Applicability
- Two-Color Detection and Quantification
- Multiplexing
- Removes Need for Film or Darkroom
- Eliminates Enzymatic Detection

Disdvantages

- Labor Intensive/Not Automated

Top Applications

- Cell-Based Assays
- Protein Detection
- Nucleic Acid Detection
- Protein Arrays
- RNAi Analysis

Biacore

Biacore™ T200

This innovative platform is used in immunogenicity studies to analyze and characterize anti-drug antibodies (ADAs) and molecular interactions related to kinetics, specificity, and concentration. It is also leveraged in the monitoring and characterization of ADAs in pre-clinical and clinical assay development, as well as for isotyping.

HOW IT WORKS

The Biacore platform monitors molecular interactions in real time by using a non-invasive label-free technology. Its detection principle is based on surface plasmon resonance (SPR) that is sensitive to changes in refractive index within about 150 nm from the sensor surface. The technology reacts to changes in the concentration of molecules at the sensor surface as molecules bind to or detach from the surface.

To study the interaction between two binding partners, one partner is attached to the surface and the other is passed over the surface in a continuous flow of sample solution. The SPR response is directly proportional to the change in mass concentration close to the surface. As such, Biacore can be used for the characterization of ADAs, the measurement of therapeutic monoclonal antibodies to Fc-gamma receptors, and for membrane protein studies such as the interaction of G protein-coupled receptors (GPCRs) with their ligands.

WHERE BIACORE 'WINS'

Biacore is most valuable when used for investigations that are characterized by extreme kinetics, interacting partners with low molecular weights, or physiological concentrations that would otherwise be considered beyond the limits of detection without the specificity of Biacore.

Advantages

- Exceptional Specificity
- Label-Free Interaction Analysis
- High Precision in Structure-Function Relationships
- High-Quality Characterization of Biomolecular Interactions
- Reliable, Reproducible Results

Disadvantages

- No Specialized Flow Cells
- High Maintenance Costs
- Restricted Sample Volume
- No Injection of Lysates, Cells, or Particulates

Top Applications

- Immunogenicity
- ADA Monitoring
- ADA Characterization
- Isotyping

ImmunoCAP

ImmunoCAP® Specific IgE

This platform is used to determine drug induced IgE-mediated immune responses, supporting the diagnosis of allergic reaction against biologicals. It is used to determine site infusion reaction that is mediated in IgE, and enables IgE antibody development to be detected at an early stage, indicating sensitization—even before clinical symptoms have developed.

HOW IT WORKS

The technology used in the ImmunoCAP platform enables a high binding capacity per mg cellulose in combination with an optimal amount of cellulose in each solid phase. This ensures binding of all relevant antibodies, regardless of antibody affinity, still giving low non-specific binding.

Anti-IgE, covalently coupled to the solid phase, reacts with the total IgE in the patient serum sample. After washing, enzyme-labeled antibodies against IgE are added to form a complex. After incubation, unbound enzyme-labeled anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The fluorescence is directly proportional to the concentration of IgE in the serum sample.

WHERE IMMUNOCAP 'WINS'

This platform is most valuable when used in studies that require a very sensitive IgE detection in the low ng- or pg range with high precision. Because of its automated processing, the platform is able to provide accurate, standardized, and reproducible test results.

Advantages

- High Accuracy
- High Sensitivity
- High Drug Tolerance
- Automated Processing
- Standardized, Reproducible Results

Disdvantages

- Costly for Clinical Applications

Top Applications

- Immunogenicity
- Evaluation of IgE-mediated Type I Hypersensitivity Reaction Against Biologicals

ELISPOT

Enzyme-Linked ImmunoSpot

ELISPOT (Enzyme-Linked ImmunoSpot) is used to visualize the secretory product(s) of individual activated or responding cells to analyze the frequencies of rare antigen-specific cells within a test population.

HOW IT WORKS

ELISPOT assays employ the sandwich enzyme-linked immunosorbent assay (ELISA) technique, where either a monoclonal or polyclonal antibody specific for the chosen analyte is pre-coated onto a PVDF (polyvinylidene difluoride)-backed microplate. Freshly isolated, thawed, or cultured cells are plated together with the antigens of interest and incubated to allow for the activation of the antigen-specific T cells and the induction of their cytokine secretion.

As the antigen-specific cells are activated, they release the cytokine, which is captured directly on the membrane surface by the immobilized antibody. The visualization of the cytokines secreted by individual T- or B-clones are achieved by enzyme-conjugated or fluorescence-based substrates. The fluorescence-based method allows a multiplex analysis of antigen-specific clones. The spots are then counted with an automated ELISPOT reader system.

WHERE ELISPOT 'WINS'

This platform is considered among the most useful for determining cell-mediated immunity because of its sensitivity and accuracy in detecting rare antigen-specific T cells (or B cells). ELISPOT is also valuable for immune response monitoring, epitope discovery, and helper T cell response evaluation.

Advantages

- High Sensitivity
- Unique Method of Capturing and Secreting Cytokine
- Single Cell Detection and Enumeration
- Adaptability to Automation
- Multiplexing

Disdvantages

- Limited Availability of Antibodies
- Amount of Secreted Cytokine per Cell Cannot be Quantified
- Costly Compared to ELISA

Top Applications

- Immunogenicity
- Immune Response Monitoring
- Epitope Discovery
- Helper T Cell Response Evaluation

LightCycler

LightCycler 480 Instrument II

The LightCycler platform provides high-quality methods for gene detection, gene expression analysis, genetic variation analysis, and array data validation, yielding qualitative and quantitative results for the detection of nucleic acids, mutation scanning, and SNP analysis.

HOW IT WORKS

LightCycler is a plate-based real-time polymerase chain reaction (PCR) amplification and detection platform which monitors the amplification of a targeted DNA molecule during the PCR. Because monitoring is done in real-time, and not at the end as in conventional PCR, LightCycler can be used to accurately evaluate gene quantification and genetic variation analysis with a high rate of reliability.

The LightCycler 480 Instrument II platform enables high-performance at medium- to high-throughput with 96- or 384-well plates. It boasts a special arrangement of optical components to ensure the uniform collection of signals across the plate, as well as an innovative PCR thermal block cycler design to precisely control temperature, and makes analysis independent of the sample position on the plate.

WHERE LIGHTCYCLER 'WINS'

The Lightcycler platform is ideal for rapidly and accurately performing assays for gene quantification, specific to gene detection, absolute quantification, and relative quantification / gene expression analysis. It can also be leveraged for genetic variation analysis, allowing for melt-curve genotyping, endpoint genotyping, high-resolution melting (HRM), and multiple plate analysis.

Advantages

- High Accuracy
- High Sensitivity
- Single and Multi-Color Applications
- Reliable, Reproducible Results
- Excellent Well-to-Well Homogeneity
- Simultaneous Data Capture Across Whole Plate
- Multiplexing

Disdvantages

- Costly Method
- Complex Software

Top Applications

- Gene Quantification
- Gene Variation Analysis

Randox

Randox RX Daytona+

The Randox RX Daytona platform is a fully automated, random access clinical chemistry analyzer used to perform both routine and specialized testing, as well as emergency STAT sampling.

HOW IT WORKS

This platform automates the running of assays on clinical samples such as blood serum, plasma, urine, and cerebrospinal fluid to detect the presence of analytes relating to disease or drugs. Photometric or ISE testing is used to determine the concentration of analyte, which commonly include enzymes, substrates, electrolytes, specific proteins, drugs of abuse, and therapeutic drugs.

The Randox RX platform runs colorimetric and UV photometric methods at twelve different wavelengths from 340 to 800 nm, with monochromatic, bi-chromatic, endpoint, kinetic, ISE, sample blanking, and reagent blanking assay options. In the analyzer, separate sample and reagent pipettes minimize the risk of contamination and carryover, and dual 5-speed Teflon coated stirrers are used to optimize mixing of each assay, both supporting high accuracy analysis.

WHERE RANDOX RX DAYTONA 'WINS'

The Randox RX Daytona platform is ideal for mid-volume clinical chemistry testing, consolidating both routine and esoteric tests onto one platform. This can include assays for clinical, veterinary, toxicology, protein, and research applications. Its unique loading hatch also allows for emergency samples to be analyzed rapidly as needed.

Advantages

- High Precision
- High Throughput
- Robust and Rugged
- Automated Analysis
- Reliable, Reproducible Results
- Large Test Menu
- Multisampling
- Adaptability to Automation
- 510(k) Approved Assays

Disadvantages

- Risk of Contamination and Carryover
- Only Ideal for Mid-Volume Testing

Top Applications

- Clinical Chemistry Testing
- Biomarkers
- Toxicology Studies

Luminex

Bio-Plex® 200 Multiplex Immunoassay System

Based on the principles of flow cytometry and powered by Luminex xMAP technology, the Bio-Plex platform uses laser-based technology to enable simultaneous measurement of up to 100 analytes in a single microplate well.

HOW IT WORKS

This Bio-Plex platform utilizes xMAP technology licensed from Luminex to deliver its multiplexed assay capabilities. This analyzer combines advanced fluidics, optics, and digital signal processing with Luminex's proprietary technology to perform discrete assays on the surface of color-coded beads known as 'microspheres'. It employs fluorescent methods for detection, using the bead sets to identify analytes, and detection antibodies to measure the quantity of analyte. The use of different colored beads allows for simultaneous detection of many analytes in the same sample, and laser excitation is employed to determine analyte concentration.

The platform is able to read and quantitate bead events individually, and can perform many assays on each sample. For example, a 30-plex kit can obtain up to 3,000 data points a day on up to 100 samples.

WHERE LUMINEX BIO-PLEX 'WINS'

Luminex is ideal for bioanalytical applications that require both high plex and high throughput at the same time. It is able to yield dramatically more information from rare and / or limited samples, and decipher complex interrelationships among proteins.

Advantages

- Multiplexing
- High Speed and Throughput
- Reduced Sample Volume
- Versatility and Flexibility
- High Accuracy
- Reliable, Reproducible Results
- Cost and Labor Savings Over Traditional ELISA or Western Blot

Disadvantages

- Challenges with Sensitivity at Very Low Analyte Concentration Levels
- Specificity Challenges Based on Quality of Antibodies

Top Applications

- Biomarkers
- Cell-Based Assays

PLATFORM EVALUATION WORKSHEET

Use this helpful tool to prioritize the parameters most critical to your assay project. The weighted results will help guide you to the platform that best supports and balances analysis requirements, budgets, and timelines.

The worksheet uses a weighted numbering system to help you prioritize between assay performance needs based on sample profile realities, cost, and speed requirements.

	Project Parameters	Project 1	Project 2	Project 3	Project 4
Assay Performance Requirements	Level of Sensitivity				
	Level of Precision				
	Breadth of Dynamic Range				
	Robustness and Ruggedness				
	Priority Level				
Sample Profile	Sample Complexity				
	Sample Size				
	Multiplexing Need				
	Throughput Volume				
	Priority Level				
Time & Cost Requirements	Automation Capabilities				
	Total Assay Tme				
	Ease of Implementation				
	Cost of Implementation				
	Priority Level				
	Other				
	Possible Platforms				

CONCLUSION

By evaluating your platform technology options from all angles, you can foster your bioanalytical success from the start. It takes a thorough review of your project requirements, and a strong working knowledge of the instrumentation at your disposal, to make the selection that will jumpstart your competitive advantage.

The development process will be greatly streamlined if you begin your study on a platform that can support your large molecule innovation all the way to market—and improve accuracy, throughput, and turnaround times along the way. Compare these aspects against costs, quality, and the promise of your biologic candidate, and the optimal choice will become clear.

If you are considering any of the platforms outlined in this Guide for your next bioanalytical project, look to BioAgilytix as a potential CRO. A proven partner to world-leading pharmaceutical and biotechnology companies, BioAgilytix boasts one of the most comprehensive suites of advanced platforms of any bioanalytical lab. Its veteran team possesses deep scientific expertise that allows them to be impartial in the way they utilize.

References:

1. Bioanalytical Method Development and Validation of Biosimilars: Lessons Learned, MOJ Immunology, Volume 1, Issue 1, 2014
2. <http://www.piercenet.com/method/overview-elisa>; accessed September 22, 2014.
3. <http://www.slideshare.net/amitgajjar85/elisa-14027063>; accessed September 22, 2014.
4. <http://cvi.asm.org/content/16/3/387.full>; accessed September 22, 2014.
5. <http://www.randox.com/rx-daytona.php>; accessed September 22, 2014.
6. http://www.perkinelmer.com/resources/technicalresources/applicationsupportknowledgebase/delfia/delfia_immunoassay.xhtml; accessed September 22, 2014.
7. <http://www.bioagilytix.com/resources/publications/ligand-binding-assays-in-the-21st-century-laboratory-platforms>; accessed September 22, 2014.

ABOUT BIOAGILYTIX

BioAgilytix is a leading bioanalytical testing laboratory specializing in large molecule bioanalysis. Located in North Carolina's Research Triangle Park, BioAgilytix provides services supporting the development and release testing of biologic therapeutics, including immunogenicity, pharmacokinetics, biomarkers, and cell-based assays. BioAgilytix offers assay development, validation, and sample analysis under non-GLP, spirit-of-GLP, and GLP, as well as product release testing under GMP.

BioAgilytix's team of highly experienced scientific and QA professionals ensures high quality science, sample and data integrity, and regulatory compliance through all phases of clinical development, and is a trusted partner to 6 of the top 10 global pharmaceutical and biotechnology companies.



 www.bioagilytix.com
 [@BioAgilytix](https://twitter.com/BioAgilytix)
 [linkedin.com/company/bioagilytix](https://www.linkedin.com/company/bioagilytix)

2300 Englert Drive Durham, NC, 27713
919-381-6097 | info@bioagilytix.com