



# 2005 Immunoassays Report

Biocompare Surveys and Reports

Published December 9, 2005

# Table of Contents

I. Report Introduction.....	1
II. Survey Methodology.....	2
III. Market Overview.....	3-4
V. Conclusion/Recommendations.....	5
VI. Appendix I: Questionnaire.....	6-10



# Report Introduction

The 2005 Immunoassay Report is composed of an immunoassay market overview and an introduction to the 2005 Immunoassay Survey, containing questions about the use of immunoassays and supplier information, as well as purchasing trends in this research area. The report also includes a comprehensive discussion of the survey results and conclusions and recommendations drawn from both an immunoassay market analysis and the survey data. The market overview delves into the shift of both academic and industry scientists to proteomics research and how advances in immunological approaches further fuel the demand for reagents, kits, and instruments in molecular analysis. Citing the immense potential of clinical diagnostics, the market for immunoassays has tremendous growth possibilities but is currently stymied in that immunoassay research products are failing to keep pace with the revenue growth of major pharmaceutical companies. Driven by high-throughput applications and the need for miniaturization, immunoassays have expanded the number of pertinent targets and fluorescent detection methodologies available. Bead-based protocols have also contributed to the increase in the widespread use of immunoassays, furthering revenue growth in such areas as molecular diagnostics. Immunoassays are expected to comprise 75% of the molecular diagnostics market by 2009, an increase of approximately \$6 billion in in vitro diagnostic technologies alone.

The 2005 Immunoassay Survey is designed to provide life science vendors of antibodies and other immunoassay products with information about the supplies that researchers are using and their plans for future purchases. Data were gathered from questions regarding the types of immunoassays used, the suppliers preferred for those types of immunoassays, the preferred immunoassay kit configurations, the sample types and species studied and how many are analyzed, the types of detection methods used, the analyte types and numbers measured, the most important features of immunoassays, researcher purchasing plans in terms of product type and time frame, the problems and limitations encountered while using immunoassays, and questions concerning the use of multiplex immunoassay products. With this information, suppliers will be better able to focus product development in areas of particular interest to current immunoassay researchers and to target their marketing and advertising campaigns in specific product areas, as well as direct customer attention to their specific immunoassay product materials. A more thorough understanding of the immunoassay market will permit companies to plan realistic goals for directing growth in the immunoassay product arena and forecast their plans for increasing immunoassay market share more accurately.

# Survey Methodology

The 2005 Immunoassay Survey consisted of 24 questions. Of these, 14 included "other" as an answer choice, providing an opportunity for survey participants to specify and elaborate their answers. Demographical information was gathered from 5 questions and from addresses submitted by survey responders. The survey was administered on-line from November 14th – 18th, 2005, and the data tabulated and presented here.

# Market Overview

The immunoassay market looks promising as researchers in both academia and industry shift their focus from genomics to proteomics. Maximizing the advantages of available technologies, researchers are pushing the envelope in isolating, purifying, analyzing and characterizing proteins. Immunological approaches to examining other molecular species, such as aptamers and carbohydrates, further fuel the demand for reagents, kits and instruments. Along with the immense potential of clinical diagnostics, the market for immunological assays could possibly see immense growth in the not-too-distant future.

Despite the rosy outlook, manufacturers and suppliers still face a host of challenges. Pharmaceutical companies, who are the biggest consumers of immunoassays, are failing to increase their R&D budgets as quickly as expected in light of growing revenues, according to Frost & Sullivan<sup>1</sup>. Pharmaceutical company mergers, which lead to decreased R&D budgets, exacerbate this lack of growth. Also, primary customers, academic and government researchers, are cutting back on purchases as government agencies, such as the National Institutes of Health, experience budget reductions. However, spending on drug discovery efforts should increase after 2007 when drug sales are expected to grow 10% annually, according to Kalorama Information<sup>2</sup>, publishing division of MarketResearch.com.

Products with greater potential for growth include innovative reagents specifically designed to facilitate functional genomics and proteomics, including those used for immunoassays. In addition, companies can also boost sales "by developing solutions that incorporate a company's existing suite of products," such as off-the-shelf kits, said Isaac Meek, an industry analyst with Frost & Sullivan. "The loss in customer base can be reclaimed by offering innovative, emergent technologies and devising new fields of application for existing technologies to attract customers, even among cost-conscious sectors."

Antibodies, the crux of all immunoassays, brought in \$374 million of revenue in 2003, according to Frost & Sullivan<sup>3</sup>. Revenue is expected to increase at a compound annual growth rate of 6.4%, which also includes revenue from restriction enzymes, nucleic acid isolation products, cell culture media and RNAi-related products. Antibodies for therapeutic and diagnostic applications could generate an estimated \$15 billion in 2005, according to the Business Communications Company<sup>4</sup>. With an average annual growth rate of 11.5%, those revenues should reach \$26 billion by 2010.

Primary screening for drug discovery depends heavily on immunological assays, including cell-based and high content assays, assays for pertinent targets and those involving fluorescent probes. Screening assays brought in combined revenues of \$840 million worldwide, according to Kalorama Information<sup>5</sup>. Growing 10% annually, revenues should reach \$1.24 billion in 2008. Kalorama indicates that companies including Sigma, BD, R&D Systems, Invitrogen and Pierce control 50% of the market.

The high-throughput needs of drug discovery and proteomics drove the adoption of microtiter plates. Currently, 96- and 384-well plates have found a place in most labs. Plates and other consumables, along with workstations, automated liquid handling systems and readers brought in revenues of \$965 million in 2003 and are expected to grow at an annual average rate of 11% to \$1.465 billion in 2007, according to Kalorama Information<sup>6</sup>. Leading companies include PE, Beckman, Tecan, Molecular Devices, Corning, BD Labware, Nunc and Greiner.

The continued push for speed helped to create momentum for miniaturization and the use of chips. As protein arrays emerge from concept to reality, revenues are expected to increase to a projected \$500 million in 2008 from \$122 million in 2002, according to Bioprospectives<sup>7</sup>. Frost & Sullivan Analyst S. Ravi Shankar estimates that the world market for protein arrays will grow at a compound annual growth rate of 31% through 2009. The leading companies include CIPHERGEN, Biacore and Luminex, each of which have a market share of 29%, 25% and 12%, respectively, according to Shankar. Other arrays are also experiencing enthusiastic acceptance. Revenues from cell arrays are expected to grow from \$65 million in 2004 to \$365 million in 2010, according to Kalorama Information<sup>8</sup>. While tissue arrays brought in a mere \$5 million in 2004, they are expected to have sales of \$400 million by 2010.

"Arrays allow researchers to conduct experiments that they previously didn't think were possible," said Sinead Igoe, an industry analyst with Frost & Sullivan. "Through the use of arrays, researchers are able to study a greater number of systems at a greater speed and with more precision."

## Market Overview (cont'd.)

The rapid rise of bead protocols demonstrates the need for ever faster immunological methods of investigation. With beads such as the xMAP microspheres of Luminex Corp., which are color-coded to maximize multiplexing potential, researchers can exponentially multiply their efficiency. "Luminex's groundbreaking xMAP technology, with its unique versatility to perform both DNA and protein-based assays, has made its technology highly sought after in the clinical diagnostics and life science industries," said Martin Nejat, an industry analyst with Frost & Sullivan. "Featuring a flexible, open-architecture design, the xMAP technology provides a wide range of applications."

The widespread acceptance of beads also stems from the substrate's adaptability with the rapid processing of flow cytometers. With its popularity "based on its automation and multiplexing versatility, the power of flow cytometry is such that the technology can be used for any test procedure that involves particle counting and analysis...of extremely large number of particles, [which] gives flow cytometry flexibility and sensitivity," according to Kalorama Information<sup>9</sup>, which estimates that sales of flow cytometry will reach 1.3 billion by 2008.

In the world of diagnostics, nucleic acid-based tests compete with immunoassays for attention. While sales of nucleic acid-based tests accounted for 13% of total revenue from all molecular diagnostics in 2003, sales are estimated to account for 25% in 2009<sup>10</sup>, according to Drug & Market Development Publications Inc. On the other hand, Drug & Market Development indicates that immunoassays will account for 75% of the market in 2009, after making up 87% in 2003. Sales of infectious disease diagnostics make up the largest source of revenue for immunoassays, bringing in \$3 billion in 2003. Increasing options in point-of-care diagnostics will stimulate sales growth in immunoassay-based diagnostics. Potential for growth also hinges upon the discovery of disease biomarkers, which could be amenable to immunoassay-based diagnostics for conditions including cardiovascular disease, cancer, prenatal screening and Alzheimer's disease. In total, the worldwide market for in vitro diagnostics was worth \$24.2 billion in 2003 and is expected to climb to \$30.8 billion in 2009.

- 
1. "U.S. Research Biochemicals Market," Frost & Sullivan, February 2004.
  2. "Early Stage Drug Discovery 2004: Combi-chem & High Throughput Screening Revisited," Kalorama Information, June 1, 2004.
  3. "U.S. Research Biochemicals Market," Frost & Sullivan, February 2004.
  4. "Dynamic Antibody Industry," Business Communications Company, August 2005.
  5. "Early Stage Drug Discovery 2004: Combi-chem & High Throughput Screening Revisited," Kalorama Information, June 1, 2004.
  6. Ibid.
  7. "Protein Biochips: Parallelized Screening for High-Output Biology," Bioperspectives, August 2004.
  8. "U.S. Market in Analytical Chip Technology 2nd Edition," Kalorama Information, June 1, 2005.
  9. "Cell-based Diagnostics," Kalorama Information, January 1, 2005.
  10. "Molecular Diagnostics: Transforming the Pharmaceuticals Market," Drug & Market Development Publications, Inc., July 2004.

# Conclusions and Recommendations

The data gathered from the 2005 Immunoassay Survey indicate that life science researchers are using immunoassay applications primarily for basic research and protein-based applications, consistent with marked shifts in scientific research trends. ELISAs are the clear immunoassay favorite, with R&D Systems and BD Biosciences topping the preferred ELISA vendors and strongly competing for immunoassay market share in general. The survey data clearly suggest where suppliers should concentrate their efforts. Researchers prefer preconfigured kits with human reagents – a focused trend toward immunoassay growth in clinical and molecular diagnostics.

While vendors face general challenges in terms of sales revenue, there is a clear directive for primary screening in drug discovery venues for immunoassays, including cell-based and high-content assays. Such screens brought in combined revenues of more than \$800 million in 2004 and are expected to grow 10% annually. BD Biosciences and R&D Systems, along with other immunoassay players such as Sigma, Invitrogen, and Pierce, control 50% of this market.

Microtiter plates, particularly the 96-well varieties, are important consumables for high-throughput drug discovery and proteomics. Such applications continue to create momentum for increased speed and miniaturization in current technologies, culminating in the expanding use of and demand for microarrays. Growth revenue for microarray technologies is predicted to more than quadruple from \$122 million in 2002 to \$500 million in 2008. Revenue growth for tissue arrays alone, while grossing \$5 million in 2004, are expected to top \$400 million by 2010.

Multiplex technologies will foster faster and more high-throughput applications and are clearly where the immunoassay field is headed. Advances in molecular diagnostics are believed to hinge on such developments and immunoassay companies are well-advised to target future product development efforts in this area.

# Appendix I: Questionnaire

## In what type of institution do you work?

- Private Research
- Government
- Biotech
- Pharmaceutical
- Clinical Diagnostic Testing
- Academic
- Other

## Which title best applies?

- Professor/Instructor
- Process Engineer
- Business Development Director/Manager
- Research Director/VP of Research
- Department Head
- Technician/Research Assistant
- Account Manager
- Graduate Student
- Staff Scientist
- Principal Investigator
- President/CEO/Owner/VP
- Lab Director/Chief Scientist
- Postdoctoral Fellow
- Procurement Manager
- Consultant
- Other

## Which best describes your purchasing authority?

- Authorize
- Recommend
- Evaluate
- No Purchase Role

## What is your principle area of research or work? (check all that apply)

- Bioinformatics
- Microbiology/Virology
- Immunology
- Genomics/Genetics
- Bioengineering
- Neuroscience
- Cell Biology
- Diagnostics/Pathology
- Drug Discovery
- Administration
- Proteomics
- Purchasing
- Biochemistry
- Marketing/Sales
- Pharmacology/Toxicology
- Molecular Biology
- None of the Above
- Other (please specify)

## Do you currently use immunoassays in your research?

- Yes
- No (exited from survey)

**For what are you currently using immunoassays?**

- Basic Research
- Biomarker development/screening
- In vitro diagnostics
- Infectious disease testing
- Isotyping
- Lead characterization
- Protein expression analysis
- Other (please specify)

**What type(s) of enzyme immunoassay do you currently use in your research? (check all that apply)**

- Bead-based multiplex assays
- EIA
- ELISA
- ELISpot
- Fluorescence polarization assays
- RIA
- Other (please specify)

**What supplier of the assay types you chose in the previous question do you prefer to use? (will loop through the selections made in the previous question)**

- |                      |                                 |                          |
|----------------------|---------------------------------|--------------------------|
| - Abazyme            | - Calbiochem                    | - Perkin Elmer           |
| - Alpcoc             | - Cayman Chemical               | - Qiagen                 |
| - Antigenics America | - Cell Sciences                 | - R&D Systems            |
| - Assay Designs      | - Cell Signaling Technologies   | - Sigma                  |
| - BD Biosciences     | - Diagnostic Systems Laboratory | - Stressgen              |
| - Bender MedSystems  | - Endogen (Pierce)              | - Upstate/Chemicon       |
| - Bio-Rad            | - LINCO                         | - Other (please specify) |
| - BioSource          |                                 |                          |

**Which of the following immunoassay kit configurations do you typically purchase?**

- Complete/preconfigured Kit (includes antibodies, coated plate, substrate, etc.)
- Development/construction Kit (includes only antibodies)
- Other (please specify)

**What sample types/species are you studying in your research? (check all that apply)**

- Serum – human
- Serum – mouse
- Serum – rat
- Serum – non-human primate
- Serum –other
- Plasma – human
- Plasma – mouse
- Plasma – rat
- Plasma – non-human primate
- Plasma –other
- Cell lysate – human
- Cell lysate – mouse
- Cell lysate – rat
- Cell lysate – non-human primate
- Cell lysate – other
- Cell culture supernatant - human
- Cell culture supernatant - mouse
- Cell culture supernatant - rat
- Cell culture supernatant – non-human primate
- Other

**What type(s) of detection methods do you primarily use? (check all that apply)**

- Colorimetric
- Chemiluminescent
- Fluorescent
- Radioisotope
- Other (please specify)

**In which of the following categories do you use immunoassays for measuring analytes? (check all that apply)**

- Angiogenesis
- Apoptosis
- Cell Adhesion
- Cell Cycle
- Cell Signaling/Signal Transduction
- Cytokines and Growth Factors
- Cytoskeleton
- Glycoproteins/Glycobiology
- Neurobiology
- Nuclear Function
- Oxidative Stress
- Phosphatase
- Phospho Amino Acid
- Stem Cell
- Transcription Factors/Regulation
- Translational Control
- Other (please specify)

**Do you currently use or plan to use a commercially available ELISA kit to any of the following molecules or molecule types? (check all that apply)**

- TNF-alpha
- MIF (Macrophage Migration Inhibitory Factor)
- PSA (Prostate Specific Antigen)
- Interleukins
- None of the above

**Please rate the following immunoassay features from 1 to 5 on a scale of importance to you. (1 = Least Important, 5 = Most Important)**

- Sensitivity
- Low cross reactivity/interference
- Affordability
- Short protocol time
- Assay precision
- Reproducibility
- Dynamic range

**Which of the following products and services are you planning to purchase and what is your purchasing timeframe?**

- Within 3 months
  - 3 – 9 months
  - 9 – 12 months
  - More than 12 months
- 
- Microplate reader
  - Integrated multiplex assay system
  - Flow cytometer
  - Multiplex software
  - Multiplex assay services
- Assay design services
  - Automated microplate handler
  - Blot/sel documentation system
  - Dot/slot blotter
  - Microplate washer

**On average, how many samples do you analyze per week?**

- Less than 10
- 11 – 25
- 20 – 50
- 51 – 100
- 101 – 250
- 251 – 500
- More than 500

**How do you expect the total number of samples analyzed in your lab to change over the next 12 months?**

- Increase by > 50%
- Increase by 25% - 50%
- Increase by 10 – 25%
- Increase by 1% - 10%
- No change
- Decrease by 1% - 10%
- Decrease by 10% - 25%
- Decrease by 25% - 50%
- Decrease by > 50%

**On average, how many multiwell plates do you process per week?**

- Less than 1
- 1 – 2
- 3 – 5
- 6 – 10
- 11 – 20
- More than 20
- Not sure

**What problems/limitations have you encountered in using immunoassays? (check all that apply)**

- Adapting assay to high throughput format
- Cost of detection equipment
- Price of assay kits and/or reagents
- Time to results
- Decreased sensitivity
- Irreproducibility
- Low signal-to-noise
- Quality control
- Other (please describe)

**Do you use Luminex xMAP® technology-based multiplex immunoassay products?**

- Yes
- Not sure
- No (skip next questions)

**Which of the following bead-based multiplex assay products do you currently use?**

- Preconfigured kits
- Custom coupled beads and antibodies
- Beads for self-coupling
- Other (please specify)

**How many analytes do you typically measure within a single sample?**

- 1
- 2 – 10
- 11 – 25
- 26 – 50
- 51 – 100