Immunoassays 2008:
An End-User Survey Exploring Current Trends and Future Opportunities

Executive Summary

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Report Introduction

The 2008 Immunoassay Report is composed of an immunoassay technology overview and an introduction to the 2008 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 technology analysis and the survey data. The technology overview delves into the science behind the basic chemistry involved in immunoassays, describing the advances and limitations of this technology. The shift of much of basic research into proteomics and the increased demand for reagents, kits, and instruments in molecular analysis are key to the growth of this research area. Citing the immense potential of clinical diagnostics, the market for immunoassays has tremendous growth possibilities. Driven by high-throughput applications and the need for miniaturization, immunoassays have expanded the number of pertinent targets and detection methodologies available. Bead-based protocols have also contributed to the increase in the widespread use of immunoassays, furthering growth in such areas as molecular diagnostics. Biomarker development, another growing research area, plays into the immunoassay application market as well. With more researchers looking to increase the number of samples analyzed using this technology in the coming year, despite a difficult economic environment, the future bodes well for immunoassay suppliers across the biotechnology and life science industries.

Technology Overview

Immunoassay technologies are used for the identification and quantitation of specific analytes, using antibodies that bind a target compound or class of compounds. Concentrations of analytes are detected by sensitive reactions that can be colorimetric, fluorescent, radioactive, or chemiluminescent. A determination of the target analyte's presence and concentration is made by comparison with a standard containing the analyte at a known concentration. Concentration can be estimated roughly by the naked eye or can be determined more accurately with a photometer or spectrophotometer.

Immunoassays exploit the ability of antibodies to bind selectively to a target analyte that has a specific physical structure present in a sample matrix. Working much like a key and lock, the binding sites on an antibody attach precisely and non-covalently to their corresponding target. Because binding is based on the analyte's physical shape rather than its chemical properties, antibodies will not respond to substances that have dissimilar structures. Enzyme-linked immunosorbent assays (ELISA) are most commonly used because the technology can be optimized for speed, sensitivity, and selectivity; ELISAs have long shelf lives and are simple to use. In an ELISA, antibodies are developed specifically to bind with a selected analyte, and that selective response is used to confirm its presence in a sample. More complicated and specific immunoassays have been developed for particular applications, including fluorescence polarization, in vivo capture, and enzyme-lined immunospot (ELISPOT) assays.

Cross-reactivity is defined as the degree to which an antibody will bind to a substance other than its target, usually occurring when different compounds of similar structure can fit into an antibody's "lock." An immunoassay supplier will provide information about cross-reactivity for compounds similar to the target analyte. This information is presented in terms of the concentration of another compound that produces a detectable response (or interference) when the immunoassay kit is used. Sometimes, 100 to 1,000 times the concentration of another compound will be necessary to cause interference. The sample matrix also can produce interference. A good sampling and analysis plan will help manage interference by specifying rigorous sample preparation procedures and requiring confirmatory samples to assess whether the results of an analysis are biased.

Detection limits for immunoassays are often comparable to, or even lower than, those of conventional analytical methods. The detection limits for immunoassay analytical techniques will vary according to test kit used, the target analytes, the sample matrix, and interfering substances.

The immunoassay market has grown as both academia and industry have shifted from genomics to proteomics. Along with the immense potential of clinical diagnostics, the market for immunological assays is expected to see immense future growth.

Technology Overview (cont'd.)

Products with greater potential for growth include innovative reagents specifically designed to facilitate functional genomics and proteomics, including those used for immunoassays. Antibodies, the primary reagent used in all immunoassays, continue to expand as more researchers generate antibodies to their proteins of interest. A vast array of tags and innovative tools for expressing proteins designed for antibody production have allowed immense growth in the technologies for their ultimate detection and diagnostic utility.

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. The high-throughput needs of drug discovery and proteomics drove the adoption of microtiter plates in that 96- and 384-well plates have found a place in most labs. The continued push for speed helped to create momentum for miniaturization and the use of chips. As protein arrays find further development and use, their application for use in immunoassays will follow.

The rapid rise of bead protocols demonstrates the need for more rapid immunological methods of investigation. With bead technologies maximizing their potential in the multiplex arena, researchers can exponentially multiply efficiency. The widespread acceptance of beads also stems from the adaptability of substrates with the rapid processing of flow cytometers.

In the world of diagnostics, nucleic acid-based tests directly compete with immunoassays in the market. Proteomics applications have witnessed the lion's share of current investment dollars; they are expected to surpass such nucleic acid-based tools in the future. The present bottleneck is in validation within this clinical arena, but momentum is rising due to clear advances in detection sensitivity. Potential for growth also hinges upon the discovery of disease biomarkers, which would be amenable to immunoassay-based diagnostics for conditions including cardiovascular disease, cancer, prenatal screening, and Alzheimer's disease.

Survey Introduction

The 2008 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 primary purposes for performing immunoassays, the types of immunoassay procedures that are currently performed, the suppliers preferred for those types of immunoassays and whether those suppliers would be recommended to the responder's colleagues, the number of replicates run per sample, the sample types and species studied, the types of detection methods used, the most important features of immunoassays, researcher purchasing plans in terms of product type and time frame, the number of samples analyzed per week and whether that number is expected to change, what size multiwell plate is used and how many plates are processed per week, the importance of control standards, whether immunoassay services are used, the problems and limitations encountered while using immunoassays, and questions concerning the use of multiplex immunoassay products. If survey participants reported using multiplex assays, questions concerning the type and number of analytes measured, the preferred suppliers of multiplex assay kits and an overall rating of multiplex immunoassay suppliers, whether those suppliers would be recommended to the responder's colleagues, which instruments and bead-based multiplex assay products are used, and whether consumables and instruments are purchased from the same source were also asked. Survey participants were also asked to provide suggestions to suppliers on the design of next-generation immunoassay instruments and reagents.

With this information, suppliers will be better able to focus product development in growing areas of current immunoassay research and to target their marketing and advertising campaigns in specific product areas, as well as direct customer attention to their specific immunoassay product materials. As immunoassay technology develops, companies will be able to anticipate future product lines and set realistic goals for directing future product development.

The 2008 Immunoassay Survey consisted of 30 questions, one of which was open-ended. Eighteen survey questions 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. The survey was administered online from March 13th – 28th, 2008, and the data tabulated and presented here.

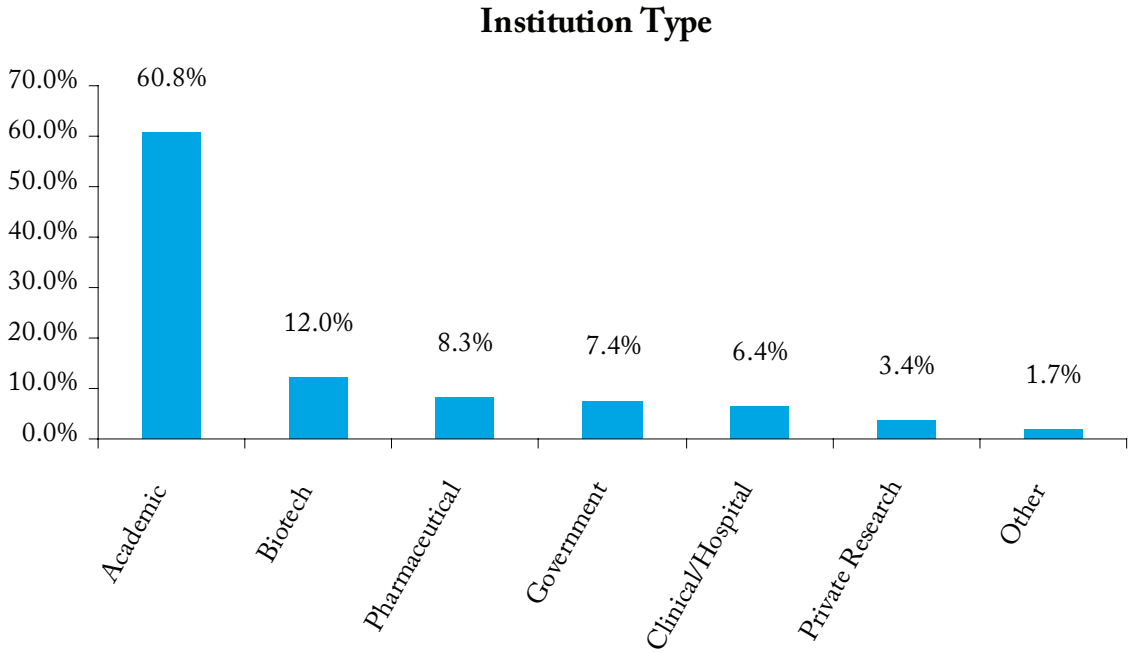
Respondent Profile

What is your institution type?

61% of the audience is from academic institutions, 20% from Biotech and Pharmaceutical companies, and 7% are from government institutions.

N = 408

Institution Type	Count	%
Academic	248	60.8%
Biotech	49	12.0%
Pharmaceutical	34	8.3%
Government	30	7.4%
Clinical/Hospital	26	6.4%
Private Research	14	3.4%
Other	7	1.7%



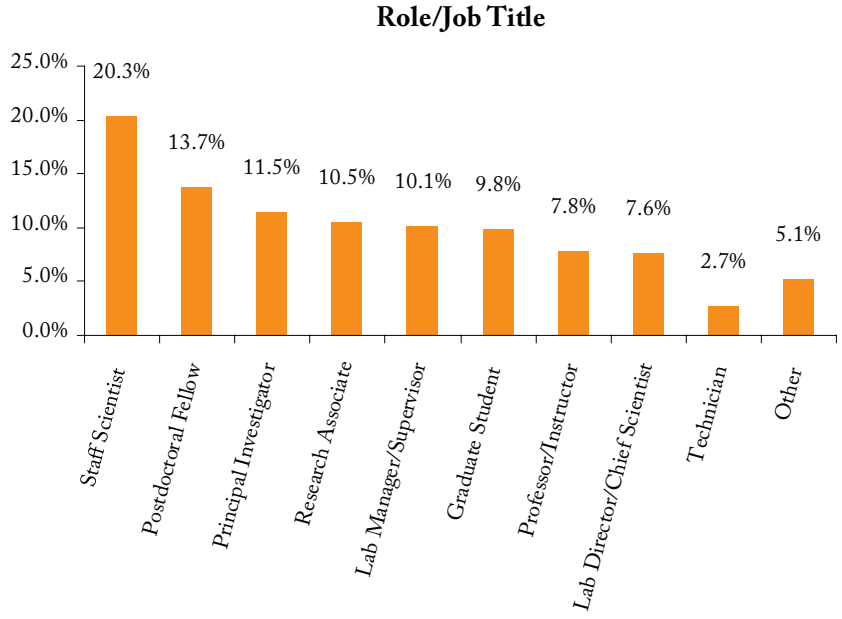
Which title best applies?

79% of survey participants work at the lab bench.*

N = 408

Title	Count	%
Staff Scientist	83	20.3%
Postdoctoral Fellow	56	13.7%
Principal Investigator	47	11.5%
Research Associate	43	10.5%
Lab Manager/Supervisor	41	10.1%
Graduate Student	40	9.8%
Professor/Instructor	32	7.8%
Lab Director/Chief Scientist	31	7.6%
Technician	11	2.7%
Department Head	4	1.0%
President/CEO/Owner/VP	3	0.7%
Business Development Director/Manager	2	0.5%
Research Director/VP of Research	2	0.5%
Other	8	2.0%

*Includes: Postdoctoral Fellow, Staff Scientist, Graduate Student, Research Associate, Principal Investigator, Technician, Lab Manager/Supervisor.

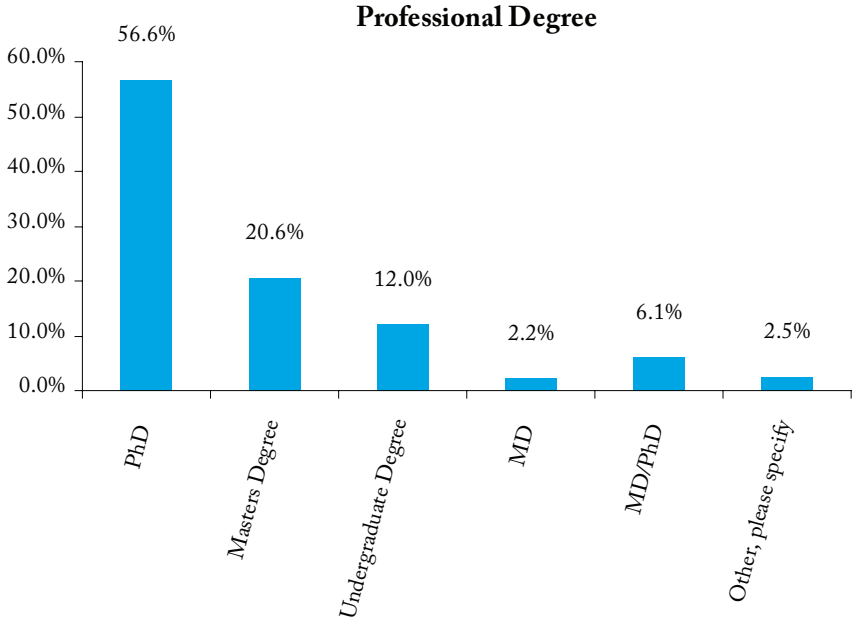


What is your highest professional degree?

86% of the survey audience has a PhD, Masters, or is an MD.

N = 408

Degree	Count	%
Ph.D.	231	56.6%
Masters Degree	84	20.6%
Undergraduate Degree	49	12.0%
MD	9	2.2%
MD/Ph.D.	25	6.1%
Other, please specify	10	2.5%



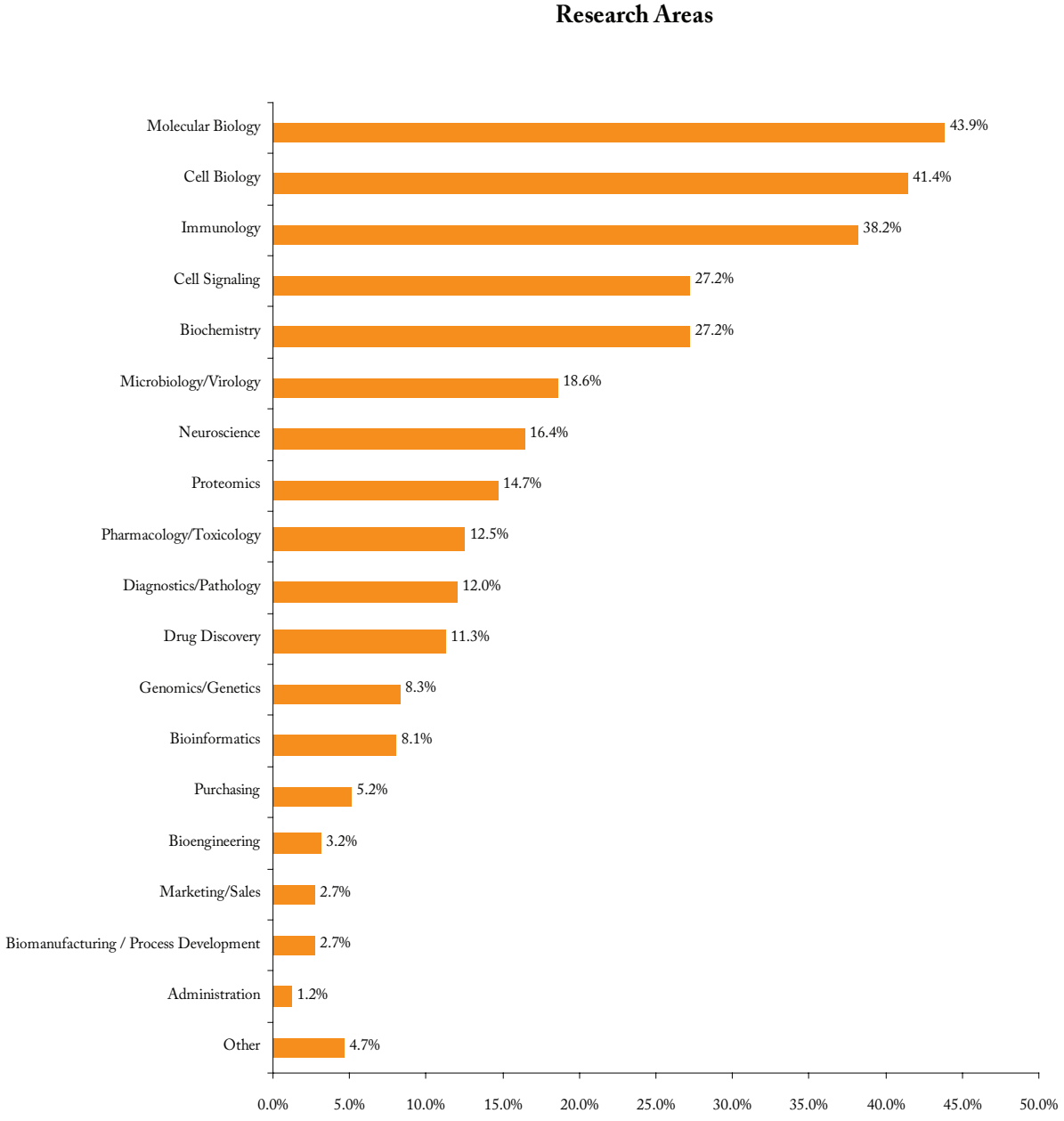
Which of the following are your key areas of research or work? (check all that apply)

Molecular Biology, Cell Biology, and Immunology are the most common research or work areas identified by survey participants.

N = 408

Research Area or Work	Count	%
Molecular Biology	179	43.9%
Cell Biology	169	41.4%
Immunology	156	38.2%
Cell Signaling	111	27.2%
Biochemsitry	111	27.2%
Microbiology/Virology	76	18.6%
Neuroscience	67	16.4%
Proteomics	60	14.7%
Pharmacology/Toxicology	51	12.5%
Diagnostics/Pathology	49	12.0%
Drug Discovery	46	11.3%
Genomics/Genetics	34	8.3%
Bioinformatics	33	8.1%
Purchasing	21	5.2%
Bioengineering	13	3.2%
Marketing/Sales	11	2.7%
Biomanufacturing/Process Development	11	2.7%
Administration	5	1.2%
Other, please specify	19	4.7%

Which of the following are your key areas of research or work? (check all that apply)

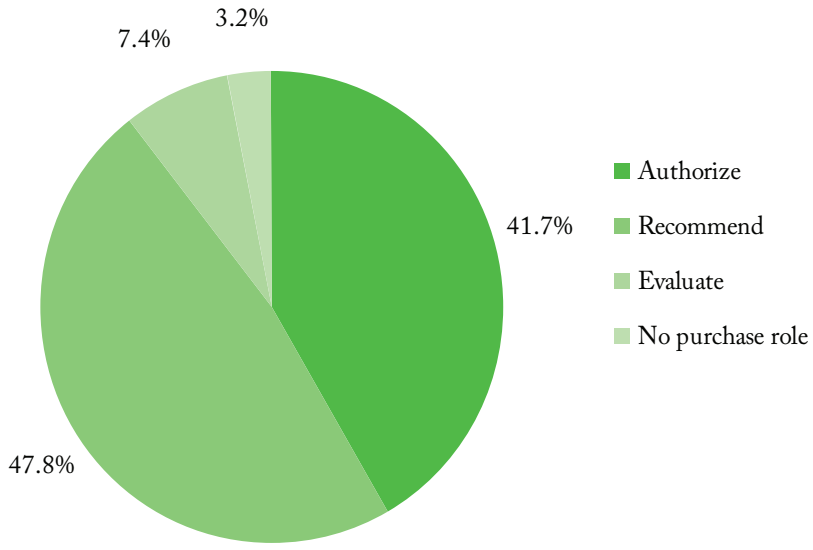


Which best describes your purchasing authority?

90% of participants either authorize or recommend purchases.

N = 408

Purchasing Authority	Count	%
Authorize	170	41.7%
Recommend	195	47.8%
Evaluate	30	7.4%
No purchase role	13	3.2%

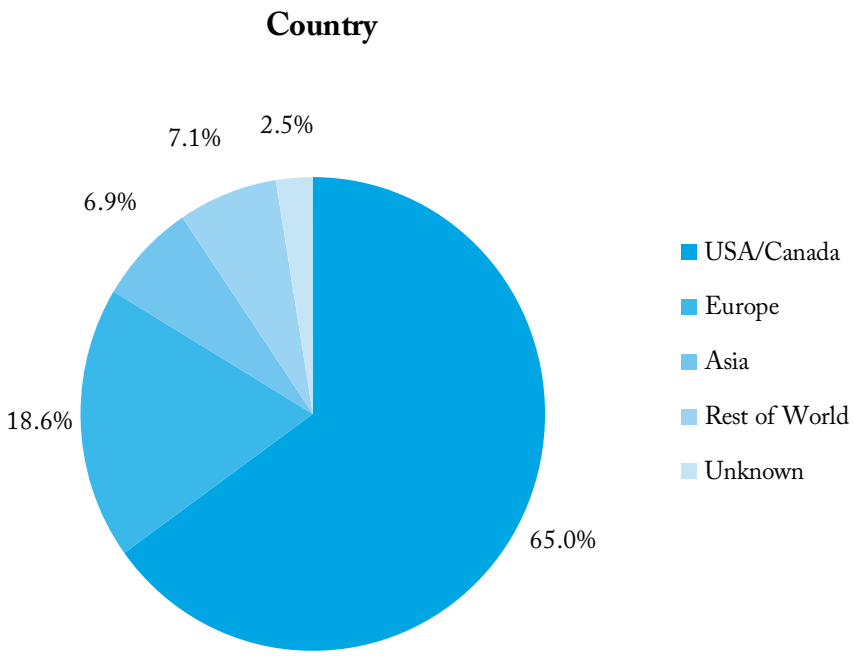


Country

65% of the survey audience is from the USA and Canada; 19% are from Europe; and 7% are from Asia.

N = 408

Country/Region	Count	%
United States and Canada	265	65.0%
Europe	76	18.6%
Asia	28	6.9%
Rest of World	29	7.1%
Unknown	10	2.5%



Appendix: Questionnaire

Immunoassay Survey

1. Do you currently use immunoassays in your research?
- Yes
- No, but plan to in the next 12 months - *screened out of survey*
- No – *screened out of survey*

2. What is your primary purpose for performing immunoassays?
- Assay Development
- Basic Research
- Biomarker development/screening
- Clinical research
- In vitro diagnostics
- Infectious disease testing
- Isotyping
- Lead characterization
- Protein expression analysis
- Immune Response
- Other (please specify)

3. What type(s) of enzyme immunoassay procedures do you currently use in your research or work? (Select all that apply)
- EIA
- ELISA
- ELISPOT
- Fluorescence polarization assays
- Immunoblotting (Western blot)
- Immunohistochemistry
- In vivo capture assays
- Multiplex assays
- Proteomic Arrays
- RIA
- Other, please specify _____
- None of the above – *screened out of survey*

4. Who are your preferred suppliers of the assay types you selected? Please select your first through third choices.
(Separate question for each assay type)
- Alpco Diagnostics
- Assay Designs/Stressgen
- BD Biosciences
- Bender MedSystems
- BioLegend
- Bio-Rad
- Calbiochem
- Cayman Chemical

- Cell Sciences
- Cell Signaling Technology
- Diagnostic Systems Laboratories
- eBioscience
- GE Healthcare (formerly Amersham)
- Immuno-Biological Laboratories, Inc
- Invitrogen (BioSource)
- Millipore (Upstate/Chemicon/Linco)
- Neogen
- Oxford Biomedical Research
- Pierce/Endogen (now Thermo)
- PerkinElmer
- R&D Systems
- Sigma
- StemCell Technologies
- Other, please specify

5. How likely is it that you would recommend these companies to a friend or colleague? Please rate on a scale of 1-10.
(Respondents will only rate the companies they selected)
1 = Not at all likely, 10 = Very likely

If performing multiplex assays, ask 6 through 13:

6. Who is your preferred supplier of multiplex assay kits?
- BD Biosciences
- Bio-Rad
- Millipore (Linco, Upstate, Chemicon)
- Invitrogen (BioSource)
- Qiagen
- R&D Systems
- Meso Scale Discovery
- Pierce/Endogen (now Thermo Fisher Scientific)
- Luminex
- Other (please specify)

7. Which multiplex instrument do you use?
- BD Biosciences
- Bio-Rad
- Luminex
- Meso Scale Discovery
- Other, please specify

8. How likely is it that you would recommend Company X (from Q6,7) to a friend or colleague? Please rate on a scale of 1-10.
1 = Not at all likely, 10 = Very likely

9. Which of the following bead-based multiplex assay products do you currently use?
- Preconfigured kits
- Custom coupled beads and antibodies
- Beads for self-coupling
- Nucleic acid – Molecular Biology formats
- Other (please specify)

10. Do you utilize the consumables and the instrument from the same source?
- Always if they offer both
- Yes, unless I need a specific analyte
- Preferred but not always
- Other (please specify)

11. Please rate the following providers on their overall system of instruments, reagents and software products on a scale of 1 to 5.
(1 = Inferior, 5 = Superior, 6 = I don't know)
- BD Biosciences
- Bio-Rad
- Millipore (Linco, Upstate, Chemicon)
- Invitrogen (BioSource)
- Qiagen
- R&D Systems
- Meso Scale Discovery
- Pierce/Endogen (now Thermo)
- Luminex
- Other (please specify)

12. How many analytes do you typically measure within a single sample?
- 1
- 2 – 10
- 11 – 25
- 26 – 50
- 51 – 100

13. How many replicates do you normally run per sample?
- Duplicates -2 per sample
- Triplicates - 3 per sample
- More than 3

14. Which of the following analyte type(s) do you measure using immunoassays? (Select all that apply)
- Acute Phase
- Allergy
- Angiogenesis
- Apoptosis
- Autoimmunity
- Cell Adhesion
- Cell Cycle
- Cell Signaling/ Signal Transduction
- Chemokines
- Cytokines and Growth Factors
- Cytoskeleton
- Diabetes
- Endocrine/Hormone
- Glycoproteins/Glycobiology
- Immune Monitoring
- Immunoregulation
- Infectious disease
- Innate Immunity
- Neurobiology
- Nuclear Function
- Oxidative Stress
- Phosphatase
- Phospho Amino Acid
- Stem Cell
- Transcription Factors
- Translational Control
- Other (please specify)

15. What sample types/species are you studying in your research? (Select all that apply)

	Human	Mouse	Rat	Non-human Primate	Other species
Serum					
Plasma					
Cell lysate					
Cell culture supernatant					
Bodily fluids (i.e. CSF, tears)					
Other, please specify					

16. What type(s) of detection methods do you primarily use? (Select all that apply)

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

17. 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
- Density of Information
- Throughput
- Sample Prep
- Automation
- Bioinformatics and readout
- Ease of Use
- Compatible with serum, plasma and lysates or supernatants
- Other (please specify)

18. 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
- Mulitplex software
- Multiplex assay services
- Assay design services
- Automated microplate handler
- Blot/gel documentation system
- Dot/slot blotter
- Microplate washer
- Multiplex bead-based assay automated washer
- Microarray reader
- Chip based platform

19. 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

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

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

21. What size multiwell plate does your lab primarily use for immunoassays?

- 384-well
- 96-well
- 48-well
- 24-well
- 12-well
- 6-well
- Other (Please specify)

22. On average, how many multiwell plates are processed in your lab per week?

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

23. Please rate the importance of control standards being included in assay kits. Rate on a scale of 1 to 5 (1 = Not Important, 5 = Very Important).

24. Does your lab use any of the following immunoassay services?
Yes, currently use
See a potential need in the future
Don't currently use and don't see any future needs

- Assay Design/Development
- cGMP Validation Services
- Target Identification/Validation
- Lead Identification/Optimization
- Screening
- Preclinical/Clinical Services

25. What problems/limitations have you encountered in using immunoassays? (Select 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
- Labor intensive
- Lack of quantifiability
- Lack of appropriate secondary antibody
- Ease of Use
- Bioinformatics
- Data Presentation
- Other (please describe)

26. Do you have any suggestions you would like to provide to suppliers when designing next generation immunoassay instruments and reagents? (open-ended)

Demographic Questions

27. In which type of institution do you work?

- Academic
- Pharmaceutical
- Private Research
- Other (Please specify)
- Biotechnology
- Government
- Clinical/Hospital

28. Which title best applies?

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

29. What is your highest professional degree?

- PhD
- Masters Degree
- Undergraduate Degree
- MD
- MD/PhD
- Other, please specify

30. Which best describes your purchasing authority?

- Authorize
- Recommend
- Evaluate
- No Purchase Role

31. Which of the following are your key areas of research or work?

- Bioinformatics
- Genomics/Genetics
- Drug Discovery
- Marketing/Sales
- Bioengineering
- Biomanufacturing /Process Development
- Microbiology/Virology
- Cell Biology
- Administration
- Pharmacology/Toxicology
- Neuroscience
- Purchasing
- Cell Signaling
- Immunology
- Diagnostics/Pathology
- Biochemistry
- Molecular Biology
- Proteomics
- Other