

Sample pages

Next-Generation Immunoassays:
A Market and Technical Analysis of Research Applications

BIO**ERSPECTIVES**

and

Bachmannconsulting

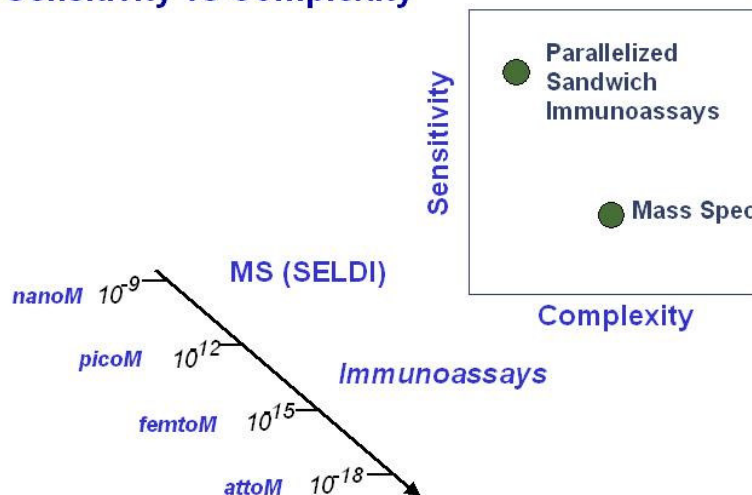
Chapter 3: Opportunities and Challenges for Next-Generation Technologies

The immunoassay is a tried-and-true research method. It is the gold standard for detecting and quantifying proteins. It has enormous versatility – it can be used to detect proteins in gels, in solutions and in tissues. It represents a large and stable market, but also presents significant opportunities for growth. As useful as immunoassays are, there is significant room for improvement.

Sensitivity

Unmet need: Sensitivity is critical. In a recent BioPerspectives survey, sensitivity was the biggest unmet need. Many proteins of interest reside below the limit of detection. The exact number is difficult to determine because researchers are not sure what they are missing, but current estimates suggest that as much as 20% of the proteome resides at levels below the current limits of detection. Researchers were able to cite numerous examples where they knew that the protein was in the sample, but was below the limit of detection.

Sensitivity vs Complexity

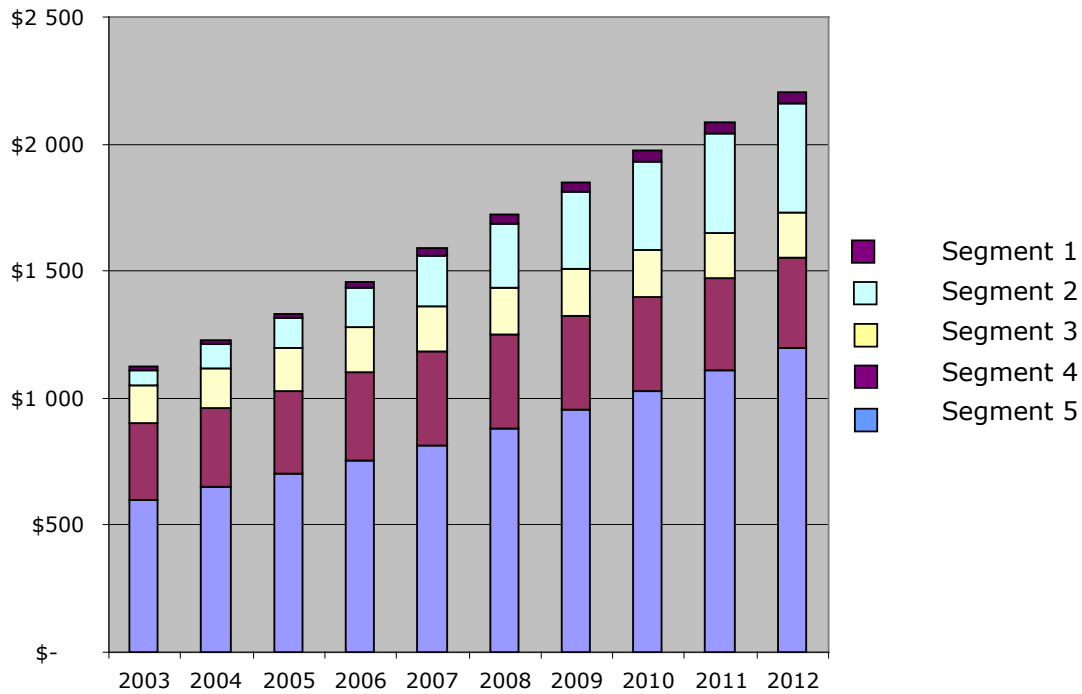


New Approaches

| Technology | Provider(s) | Analysis |
|-------------------|--------------------|--|
| Technology A | Company A | Potentially high signal-to-noise from 3-D packing, but not in widespread use. |
| Technology B | Company B | Potentially offer single molecule detection, but signal-to-noise is only as good as the antibody. |
| Technology C | Company C | Enables time-resolved fluorescence, potentially improving signal-to-noise by ability to separate background fluorescence, but difficult to use. |
| Technology D | Company D | Enables conjugation of multiple labels, but detection can involve additional steps. |
| Technology E | Company E | Potentially reduces noise by requiring the interactions of one or more antibodies, but external validation is limited. |
| Technology F | Company F | Not necessarily an improvement in sensitivity, but wide range of colors well suited to multiplexing, especially in immunohistochemistry. |
| Technology G | Company F | Raman tags have narrow spectra enabling hundreds to be multiplexed. In addition, long excitation enables signal averaging and higher signal to noise. But commercialization appears to have slowed down. |
| Technology H | Company G | Strong signal with white light, but large size can be difficult to work with. |
| Technology I | Company H | Enzymatic amplification enables production of large signal, but signal-to-noise is the challenge. |

Total Market

The total market is projected to grow from \$1.1 billion in 2003 to \$2.2 billion in 2012, a compound annual growth rate of 8%. The fastest growing sectors are expected to be Segment 1 and Segment 2. Segment 3 and Segment 4 are projected to begin to contract in a few years due to competition from Segment 2 and Segment 5. Segment 5 is projected to remain the foundation of this market, continuing to grow as a result of both the market drivers and the new technologies described above.



Luminex Corporation

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| <p style="text-align: center;">Address</p> <p>12212 Technology Blvd Austin, TX 78727, USA Tel.: +1 512-219-8020 Fax: +1 512-219-5195 E-mail: info@luminexcorp.com Website: www.luminexcorp.com</p> | <p style="text-align: center;">Overview</p> <p>Luminex Corporation develops, manufactures and markets proprietary biological testing technologies with applications throughout the life sciences industry.</p> |
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| <p style="text-align: center;">CEO/President</p> <p>Patrick J. Balthrop</p> | <p style="text-align: center;">Stage of Development</p> <p>The company's xMAP[®] system is an open-architecture, multi-analyte technology platform that delivers fast, accurate and cost-effective bioassay results to markets as diverse as pharmaceutical drug discovery, clinical diagnostics and biomedical research, including the genomics and proteomics research markets. The company's xMAP technology is sold worldwide and is already in use in leading research laboratories as well as major pharmaceutical, diagnostic and biotechnology companies.</p> |
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Corporate Information

Luminex[®] (LMNX) was incorporated in May 1995 and began commercial production of their first-generation system in 1997. The xMAP technology has been marketed since 1999 on a worldwide scale. Luminex has more than 50 partners in the pharmaceutical drug discovery, clinical diagnostics and biomedical research markets. Luminex's xMAP technology received the 2005 Clinical Diagnostics Technology of the Year Award from Frost & Sullivan. The company was named in the 2005 Deloitte Fast 500 of fastest-growing technology companies. Luminex reported consolidated revenue for the first quarter of 2007 of \$16.6 million (\$13.0 million in the first quarter of 2006).

Luminex Corporation cont'd

Technology

- The open-architecture xMAP® technology (previously known as LabMAP®) is based on color-coded beads and flow cytometry instrumentation for the analysis of up to 100 different biological assays in a single well.
- Tiny colored beads, called microspheres, are coded into 100 distinct sets. Each bead set can be coated with a reagent specific to a particular bioassay, which enables the capture and detection of specific analytes from a sample.
- Luminex has launched magnetic beads that facilitate wash steps. (Magnets can be used for separation instead of filter plates.)
- The acquisition of TM Bioscience gives Luminex more access to the diagnostic market.

Corporate Assessment

STRENGTHS AND OPPORTUNITIES

- Flexible technology is suitable for a wide range of applications throughout the drug-discovery and diagnostics fields, as well as basic research. These include, for example, the measurement of cytokines, kinase selectivity, phosphoprotein, endocrine, matrix metalloproteinases (MMP) and transcription factors, as well as allergy, autoimmune and tissue typing for clinical diagnostics.
- Luminex has more than 50 partners who provide assays for the xMAP platform. The list of companies using Luminex technology for clinical diagnostics includes: Abbott Molecular Inc., Asuragen, bmd, Bayer Healthcare, Bio-Rad Diagnostics, Celera Diagnostics, Digene Corporation, EraGen Biosciences, Focus Diagnostics, Genaco Biomedical Products, Inc., INOVA Diagnostics, Inc., ImmuneTech, Innogenetics NV, Inverness Medical, Professional Diagnostics, MICROBIONIX GmbH, Multimatrix GmbH, One Lambda Inc., Tepnel Lifecodes and Zeus Scientific Inc.

WEAKNESSES AND THREATS

- The competition is increasing, with new systems developed and commercialized by companies such as BD, Illumina, Nanoplex and others.
- Current growth is limited due to the partner model; if the partner is not pushing the Luminex business, then those assays can stagnate.
- For future growth, the company will likely need to expand beyond just instrument and reagent sales into assays. The company recently purchased TM Biosciences, as part of this strategy. The risk, however, is competing with partners who supply assays.

Luminex is currently the leading bead-based platform.