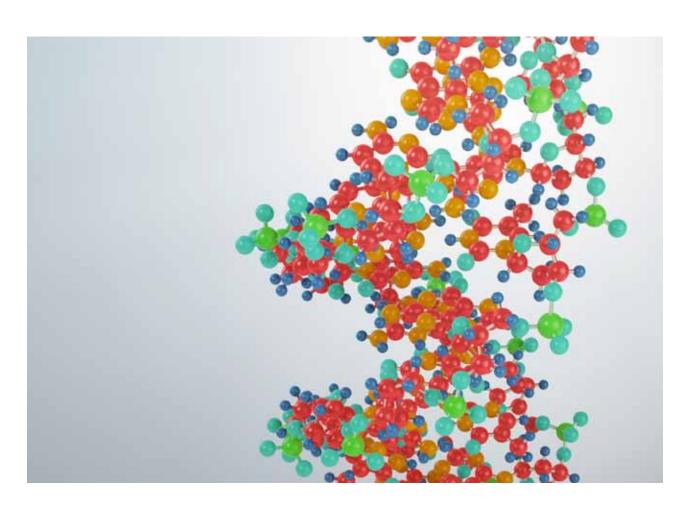
THREE TRENDS TO WATCH IN LIFE SCIENCES





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Three Trends to Watch in Life Sciences



INTRODUCTION

Healthcare is changing rapidly. Companies who provide products and services to hospitals and physicians will need to adjust their operations to change.

This brief white paper, 3 Trends to Watch in Life Sciences, looks at three of the most important trends in Life Sciences. These trends are changing how healthcare is delivered, the patient's experience and outcome, and which healthcare companies will win and lose.

- Molecular Testing drives faster results, better outcomes
- Personalized Medicine Drives Partnerships Between Dx and Drug Companies
- Next Generation Sequencing Technology Challenges Traditional Diagnostics and Clinical Practice.

These trends have been covered extensively in reports published by www.kaloramainformation.com







TREND ONE: PERSONALIZED MEDICINE DRIVES DRUG-DIAGNOSTIC **PARTNERSHIPS**

A large number of acquisitions and partnerships occurred in the in vitro diagnostics (IVD) industry over the past two years, a sign of the frenetic pace of the industry, according to Kalorama Information's latest market research study. There were at least 105 acquisitions and distribution agreements in the IVD market just in the past two years.

A number of totally disparate phenomena have come together for IVD at the same time. Human genome research is finding links between a person's genome and several lifestyle situations such as nutrition, dieting, skin conditions and other essentially non-medical conditions. This has attracted consumer product companies such as Proctor & Gamble and Nestlé to develop products and services based on IVD technologies. Decreases in life science grants have encouraged companies active in this space to migrate their technologies for clinical applications. The result is the entry of companies such as Caliper Life Sciences, Illumina, Affymetrix and Life Technologies to the diagnostics market

This trend is based on information from Kalorama Information's 8th edition of its report, "The Worldwide Market for In Virto Diagnostic Tests."

This 1,400+ page report has market size estimates for all aspects of IVD, hundreds of company profiles and trend analysis of the industry.

with products and test services. Miniaturization of traditional immunoassay and molecular test technologies has finally matured to the point where it may be ready for scale-up and then commercialization into products. This has attracted electronics companies such as Sony, Samsung, Dell Computers and Intel to invest in clinical diagnostics ventures.

"The future of the industry lies in the development of more sensitive, faster, user-friendly, IT capable devices for a host of new protein and molecular markers," said Shara Rosen, R.T. MBA, the author and lead diagnostic analyst for Kalorama Information. "No company, big or small, owns all the technology needed to develop these new tests and systems."

The IVD Industry in Segments

Kalorama segments the IVD industry into the following major categories:

- Core Lab presents topics related to clinical chemistry testing and topics related to the consolidation of routine lab work onto a single work station or instrument.
- Immunoassays include routine commodity tests that account for the majority of immunoassays performed: thyroid function, anemia markers, fertility tests, therapeutic drugs, toxicology/drugs of abuse, cortisol, insulin and common infectious diseases. These assays make up approximately 60% of the dollar immunoassay market but 75-80% of the test volume. Immunoassays are gaining importance in post genomic medicine. They are the technology used to measure the physiological elements proteins, hormones, enzymes, expressed by genes.







- Blood transfusion services use reagents and instruments to prepare blood units for transfusion to patients. Each unit is assessed for its ABO and Rh grouping and the presence of blood antibodies and is screened for the presence of pathogens.
- Blood banks use three classes of IVD products:
 - Blood grouping and typing reagents and instruments
 - Immunoassays to screen for blood borne pathogens
 - Nucleic acid tests (NAT) to screen for blood borne pathogens
- Microbiology and virology is one of the fastest growing segments of the IVD industry. Infectious diseases, primarily STDs, tuberculosis, HIV and hepatitis are the number one public health problem worldwide. In addition globalization of the world's food supply and increased world travel has introduced viruses, parasites and bacteria from emerging countries to the developed world. Further, there is pressing need for the timely and early diagnosis of hospital acquired infections that can lead to systemic infection (sepsis) and in some cases death, especially in patients in a weakened state. It is divided into five basic segments: organism identification and bacterial resistance (ID/MIC), rapid micro tests from colonies, and immunoassays for infectious diseases (lab-based and rapid), nucleic acid tests and traditional microbiology, which are detailed in our full report.
- Hematology is the study of peripheral blood and bone marrow cells in order to diagnose various diseases of the blood including leukemias, anemia and autoimmune diseases. The basis of hematology testing is the complete blood count (CBC) that provides information on blood components: hemoglobin, hematocrit, red blood cells, white blood cells, reticulocytes, platelets. The CBC is run as part of the normal work up in an annual health exam and for every inpatient and is a staple of out patient care.
- Point-of-care testing represents rapid and desktop testing devices intended for the healthcare setting and for relatively fast (though not always instant) results. POC has evolved because of the need for quick answers to time sensitive tests and the demand by consumers to have more access to lab tests. Within the health-care environment there are two major categories of end-users. One is hospitals, physician office laboratories, and other decentralized health-care facilities such as walk-in clinics and nursing homes. The second is patient self-testing.
- Molecular testing is making a valuable contribution to clinical diagnostics on many fronts. The most dynamic segment is infectious disease DNA-based tests that allow the detection of difficult to culture pathogenic bacteria or viruses. For HIV patients molecular assays have allowed physicians to fine tune their course of treatment so as to keep the virus in remission. Blood based molecular tests for early cancer detection are being actively researched and several are now available as lab developed tests. Similarly the analysis of cell free fetal DNA in maternal blood now provides noninvasive prenatal screening that is destined to replace amniocentesis.







- Histology and cytology tests are used primarily to test tissue for evidence of cancer
 cells and infectious agents. Fluids and biopsied bits of tissue are processed, placed on
 glass slides, and stained to characterize targeted cellular constructions and inclusions.
 Tissue slides are first read by technologists using microscopy. The work is highly labor
 intensive and subjective in nature. Suspicious slides are read by pathologists. At least
 this was the scenario for this market segment until the recent arrival of automation
 and immunohistochemical stains (IHC) that use fluorescent and colorimetric labeled
 antibodies to detect enzymes, proteins and other analytes in tissue.
- The coagulation cascade manages blood flow through the body by preventing clot formation and excessive bleeding, as well as dissolving blood clots when they occur. Coagulation tests include routine screening clotting time assays—prothrombin time test (PT) and activated thromboplastin time test (aPTT) that provide a gross assessment of coagulation capability. Coagulation factors have been implicated as independent factors in the development of myocardial infarction, stroke and deep vein thrombosis in some patients. With the increasing incidence of cardiovascular diseases, this discovery has brought what was a rather lackluster discipline into the limelight.

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Different trends in all of these segments are combining to push growth in the 50+ billion-dollar IVD industry. This year, the industry assessed its progress at the American Association for Clinical Chemistry (AACC) in Los Angeles. Kalorama spoke to numerous industry members. Consensus was that the market has grown but will be challenged with a sharp decline in pricing for diagnostic tests in Europe and consolidation in the U.S. that leads to price erosion.

A number of world events bode well for the future of medical devices: an aging worldwide population and demand for new hospitals in developing countries. Increasing numbers of people between the ages of 45 and 75 years in the industrialized world consume more healthcare services such as heart and cancer tests.

According to Kalorama's report, the development of IVD product choices has been a boon for medical care. But that development also puts a great deal of pressure on physicians to make the right choices and for payers to pay for new technologies that may still be unproven.

Overall in the IVD industry, a couple of trends are noted in Kalorama's most recent report:

- Slightly slower growth due to price erosion and government cutbacks in developing world (specific forecasts in the full volume)
- Hope for future growth lies in emerging markets
- Market shares have changed, but players have not, over the decade.
- Increased use of cell phone technology to transmit results
- Continued recognition of Dx technologies as a cost-saver







- The analysis of mutations of known human genes is used to diagnose common disorders, inherited diseases, or different types of cancer and can indicate the prognosis of malignant diseases.
- · Growth of molecular technologies, especially in infection treatment
- A concern with getting test results efficiently into an EMR system
- There is also a growing OTC aspect to POC testing, and a possibility of OTC HIV tests will be brought to the U.S.
- Major companies are purchasing labs and offering complex tests as services
- In the scope of this white paper, these trends are mentioned but they are detailed and substantiated in forecasts in Kalorama's full report.

As an aging society begins to use more healthcare services, cost efficiency imperatives continue to put pressure on payers, providers and suppliers which has led to strict cost/performance and care guideline directives. Kalorama suggests that some of the total market growth expected in the coming years derives from increased test usage in emerging countries. Significant growth is expected in Brazil, China and India that are investing in healthcare infrastructure and insurance coverage for a growing more affluent middle class. IVD companies are casting their nets in developing countries, where rising incomes and standards of living have sparked a new health consciousness and growing demands for quality medical care.

Industry Acquisitions and Partnerships

The report cites some examples of acquisitions that have occurred since 2010:

- Danaher Corporation purchased IVD leader Beckman Coulter
- Agilent Technologies purchased FISH/IHC leader Dako
- Roche entered a development agreement with Dexcom for its SEVEN PLUS continuous glucose monitor system and purchased the RALS IT connectivity system from Medical Automation Systems
- Abbott acquired STARLIMS lab IT system and Biofortuna's freeze-dried SSPGo HLA typing kits
- Terumo Corporation of Japan merged with CaridianBCT a blood unit processing company
- Perkin Elmer acquired Caliper Life Sciences
- Gen-Probe invested \$50 million in Pacific Biosciences, known for its SMRT sequencing platform
- · Quest purchased Celera, a maker of genetic tests

On the next page, we list some of the industry acquisitions and partnership deals that have occurred over the last two years. Kalorama's report, The Worldwide Market for In Vitro Diagnostics contains a greater detail of information, over 1,400 pages of important market data used by the industry. The title is available from Kalorama Information at:

http://www.kaloramainformation.com/Worldwide-Vitro-Diagnostic-6859416/







SELECT Diagnostics Industry Acquisitions 2010-2011

Company	Location	Action	Detail
Abbott Diagnostics	U.S.	Buy	STARLIMS Technologies Ltd, IT
AbSorber AB	Sweden	Buy	Olerup Inc., HLA organ transplant PCR
Affymetrix	U.S.	Buy	eBioscience, Inc., flow cytometry and immunoassay reagents
Agilent Technologies	U.S.	Buy	Dako, leader IHC, FISH
Axela Biosensors, Inc.	Canada	Buy	Xceed Molecular, Ziplex System for gene-expression analysis
Beckman Coulter/Danaher	U.S.	Buy	co-owner Autonomics, immunoassays
Beckman Coulter/Danaher	U.S.	Buy	Blue Ocean Biomedical, CE Marked flow reagents
Becton Dickinson	U.S.	Buy	Dynacon's (Toronto, ON) Lab Systems, microbiology automation
Becton Dickinson	U.S.	Buy	Accuri Cytometers, Inc., compact flow cytometers
Biocartis	Netherlands	Buy	Royal Philips Electronics' automated DNA/RNA platform
Bio-Rad Laboratories	U.S.	Buy	QuantaLife, digital PCR system
Danaher Corporation	U.S.	Buy	Beckman Coulter
Dexcom Inc.	U.S.	Buy	SweetSpot Diabetes Care, Inc., glucose mgmt
Diagnostica Stago	France	Buy	Trinity Biotech.s coag business, new company TCoag
Diasorin S.P.A	Italy	Buy	MUREX infectious disease immunoassays from Abbott Diagnostics
Gamida for Life Group	Israel	Buy	ELITech's Nanogen IP, arrays
GE Healthcare	UK	Buy	Clarient pathology lab
GE Healthcare	UK	Buy	SeqWright, Inc. (Houston, TX) DNA sequencing genomic services
GE Healthcare	UK	Buy	Applied Precision, Inc., (Issaquah, WA), cellular imaging
Gen-Probe	U.S.	Buy	GTI Diagnostics, HLA markers
Grifols SA	Spain	Buy	Lateral-Medion, lateral flow
		<u> </u>	immunoassays





Insulet Corporation	U.S.	Buy	Neighborhood Diabetes, Inc.,
			diabetes meter supplies
IRIS International	U.S.	Buy	BioMicro Systems FISH/
			Cytologysample prep

TREND TWO: NEXT-GENERATION SEQUENCING MOVES INTO **CLINICAL APPLICATIONS**

Continuing improvements in next-generation sequencer technologies are causing revolutionary changes in biomedical research, which are gradually translating into new clinical applications. The NIH has taken notice, and has shifted resources from basic research to more medically-oriented projects. As the cost of systems and consumables continues to drop, this has followed an exponential trend similar to Moore's Law with computer chips and transistors.

The trend of decreasing cost has actually been accelerating on a logarithmic scale; if it continues, it would lead to a cost of only \$10 per genome in around five years. Benchtop next-generation sequencers are now priced at \$50k to \$100k, compared to the \$500k to \$700k for higher end systems.

The ability to pool multiple individuals' samples in one run has allowed further savings of time and money. As a result, sequencers are expected to see widespread adoption in the next several years into a much broader range of clinical applications than before, as the scientific and regulatory hurdles are gradually addressed. The following sections provide some examples of the clinical areas showing promise.

Cancer Diagnostics and Treatment

Cancer treatment is one of the major areas where sequencers are expected to have the biggest impact in the near future. This is due to the many types of genetic aberrations involved, and the variations between cancers which can affect treatment and outcome. There is a large network of consortia and cancer genome projects, with

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varying degrees of coordination taking place. Along with the tumor itself, the circulating DNA in the blood may allow the determination of response to drugs, disease burden, and likelihood of recurrence. The latest sequencer technologies permit analysis at the level of DNA sequencing, RNA sequencing, micro-RNA sequencing, methylation, transcription factor and other regulatory protein binding; all of these are being explored as potentially valuable approaches. New technologies allowing single-cell sequencing may also be particularly useful for cancer-related applications.







HLA / MHC Complex

The human leukocyte antigen (HLA) genes, in the major histocompatibility complex (MHC) region of chromosome 6, have associations with many conditions and diseases. The Sanger sequencing of these genes has been widely used in the area of tissue transplantation already for many years, because similar alleles indicate compatibility and help to reduce the risk of rejection. The HLA genes are also involved in infectious diseases, autoimmune diseases, and adverse drug reactions, indicating many new potential applications. MHC molecules have also been the subject of studies related to odor preference in mate selection, which have suggested that partners with dissimilar MHCs may be preferred due to the increased immunity provided to the children. These regions exhibit a very large diversity in humans, with some HLA genes having thousands of known alleles.

Neonatal and Prenatal Testing

The neonatal and prenatal areas are also expected to see rapid growth in the near term. These applications include inherited genetic diseases as well as various types of aneuploidy/ trisomy. There are thousands of Mendelian disease genes known to cause a huge range of inherited genetic diseases, and more are constantly being discovered. Aneuploidy/ trisomy includes several chromosomal abnormalities such as extra or missing chromosomes; in babies, these tend to result in birth defects and developmental disorders, and more extreme aneuploidies also occur in cancer. Several companies have been offering neonatal and prenatal tests for the various trisomies, primarily by quantifying fetal chromosomes found in the maternal blood plasma. In fact, the entire fetal genome has been found to be present in maternal blood plasma. However, sequencing a complete neonatal or prenatal genome is currently only seen as necessary for serious undiagnosed conditions and for families known to have inherited genetic diseases. As the cost of sequencing continues to drop, many anticipate whole genome sequencing to become a standard test for babies; but the ethical, legal, and social complexities have yet to be worked out.

Pathogen Detection and Subtyping

Pathogen detection, subtyping, and epidemiology are expected to benefit greatly as newer and cheaper sequencer technologies appear. Sequencing is already used routinely to identify drug resistant mutations and genetic variability in viral infections. Lower cost and higher output are now allowing broader applications, such as the monitoring of healthcare associated pathogens in hospital environments (e.g. MRSA), the immediate characterization of contagious outbreaks, and other means of infection control in humans as well as agriculture. Portable devices could eventually lead to broader usage in forensics, law enforcement, civil defense and other areas.







Near Term and Long Term Prospects

There are several other clinical areas where sequencing is viewed as showing great promise in the near term. For example, pharmacogenetics and related personalized medicine applications may allow a great reduction in adverse drug reactions, which are now the primary cause of accidental death in the United States. These tests could be particularly beneficial for patients taking many drugs concurrently, such as the elderly. Consumer/ personal genomics is a related area that is evolving gradually as its usefulness becomes better understood and its complex new issues are addressed; the new approaches to preventive medicine often involve difficult questions weighing benefits, risks, and their probabilities. Collectively in the longer term, this increasing range of applications of sequencing could bring about a paradigm shift in healthcare.

New laboratory-developed tests are being introduced by CLIA-certified high-complexity labs, and the sequencer suppliers are putting their systems and test panels through the FDA 510(k) and premarket approval processes. Individual disease areas can each have their own intricacies, and the advances have been gradual. The challenges relate to the science of the diseases, the various sequencer technologies with their unique pitfalls, as well as the significant ethical issues likely to arise. Data analysis and data management can be difficult tasks. These variables will shake out as they come up in each application; meanwhile, lower-priced sequencers and consumables will allow smaller labs and organizations to adopt the technology. Clinical applications could soon become a large fraction of the sequencer market; however, the rapidly falling costs will continue to offset the growth. Long term, in ten years or more, it is foreseeable that sequencers will become ubiquitous, and patients may have the DNA in their circulating blood tested regularly to monitor multiple things at once. Portable devices are eventually expected to open up the market to doctors' offices and other completely new segments.

The rapid changes in medicine are likely to bring about many new questions and challenges. For example, the storage of an individual's sequence data, and how to ethically approach situations where a disease can be predicted but not treated, are examples of the difficult issues. Furthermore, sequence data can be used to uniquely identify an individual. The information also crosses into areas unrelated to medical treatment, such as ancestry, abilities, and other traits. Combined with the ongoing innovations permitted by the internet, it is hard to predict exactly how these things will progress over the longer term. Without a doubt, many of the clinical applications will continue moving into mainstream use as they become proven and the economics gets worked out. Due to lower regulatory hurdles, these developments will most likely occur more rapidly in Europe than in the USA.







TREND THREE: MOLECULAR TESTING ENTERS ROUTINE PRACTICE

The sixtieth anniversary of the discovery of DNA will be celebrated in 2013. On April 25, 1953 the journal Nature published the discovery of the double helix structure of DNA by James Watson and Francis Crick. Similar to many other scientific innovations, no one at that time realized that this might turn out to be one of the most significant discoveries of our time. Now virtually every segment of clinical laboratory medicine has been touched by research in genetics.

The first generation of molecular testing tools includes basic, time consuming and labor intensive techniques such as the Southern blot, DNA probes, pulsed field gel electrophoresis and capillary electrophoresis. These techniques are still used however their influence in the evolution of molecular testing has been overshadowed by the power of PCR and other amplification techniques, sequencing, mass spectroscopy, microarrays and biochips.

The full development of PCR by F. Hoffmann La Roche, Basel, Switzerland ushered in the second generation of molecular testing tools. These were first used for medical research and now play an essential role diagnostic medicine and in patient care. In 1991, Cetus sold the PCR intellectual property to F. Hoffmann-La Roche Ltd. for \$300 million. This proved to be the major building block of modern molecular testing. This is partly due to the flexibility of the technology but mostly due to Roche's liberal licensing strategy that PCR has become the most widely used method for amplifying DNA. More importantly it was the catalyst for the beginning of modern molecular testing. PCR and automated sequencing instrumentation are the tools used by the Human Genome Project and Celera Genomics Corp. (Rockville, MD) to produce the draft sequence of the human genome that was published in 2000. These tools have also been used to sequence the genome of many other animals, pathogens and nonpathogenic organisms.

In 2003 the Human Genome Project published the identification of all the building blocks in the human DNA. In all, since 2003, research has linked nearly 100 DNA variants to as many as 40 common diseases and traits. We now are in the full evolution of the third generation of molecular testing or the "next generation" of a number of molecular test solutions. These have had several common effects on molecular diagnostics that are leading to a further expansion of clinical lab testing possibilities: The primary growth drivers in the molecular diagnostics market overall, are the continued discovery of genetic markers with proven clinical utility, the increasing adoption of genetic based diagnostic tests, and the expansion of reimbursement programs to include a greater number of approved diagnostic tests. The most attractive growth areas are molecular tests for histological analyses, women's health, infectious diseases, organ transplant testing and oncology.

Significant changes in healthcare delivery herald a new era in diagnostic testing needs. This new era requires on one hand very sophisticated, sensitive assays for infectious disease management, disease detection and drug treatment decisions. On the other hand, these tests has resulted in more than 400 licensees - companies and organizations.







However, the contribution that these tests can make to patient outcome faces significant barriers including reimbursement issues; lack of standardization across test platforms; and limited quality control products and programs. Also, molecular tests, especially for inherited diseases and some FISH analyses are extremely complex. The tests provide raw data, the interpretation of which sometimes baffle even the most experienced molecular biologists.

The increasing market penetration of nucleic acid assays in the next few years is in part due to maturation of the technology itself and the development of appropriate diagnostic applications. The further success of these assays will for the most part result from the commercialization of rapid, user-friendly and economical high quality test systems and the discovery of molecular-based therapeutics that will allow for more individualization of disease management. As is often the case, technology has pushed ahead far beyond our ability to incorporate the products developed by these new technologies into healthcare delivery systems. There are a host of technical, ethical and marketing issues that may limit the development and future market penetration of gene-based diagnostic tests.

Optimism for the future benefits to modern medicine is tempered by the fact that the big payoff is still a way off. Finding the genes that can raise the risk of an illness doesn't mean you can prevent the disease. And developing a treatment for it can take years. One of the major challenges facing molecular testing is getting stakeholders including payers, physicians, researchers and regulators to work together to close the gap between research and clinical applicability. Not to dwell on the negative at this time, the ensemble of these elements create a dynamic, energetic and fast-moving environment for new tests and companies. This chapter provides an overview of the market forces and their impact on molecular Physician education is another area that could advance the use of tests.

Molecular medicine will transform the entire spectrum of disease management, from assuring the early detection of disease, to defining the prognosis of disease evolution and to predicting a patient's response to specific therapies. This applies to a number of chronic conditions cardiovascular diseases, diabetes, cancer, psychiatric disorders and drug therapy; and infectious disease medicine.

Increasing in importance are tests that use molecular profiling by sequencing technologies. These tests allow for the investigation of patterns or signatures in DNA (genetics), RNA (genomics), protein (proteomics) and even metabolites (metabolomics) associated with a phenotype or clinical outcome. Most of the research activity and innovation in molecular testing is focused on diagnosing, treating and monitoring cancer and the detection of infectious diseases. However, as more is known about disease processes, these tests will also impact patient care for other chronic diseases such as neurological conditions. autoimmune diseases, diabetes and cardiovascular diseases.







Of particular interest is the range of tests that are on the horizon. Just a year or two ago, this list would have been dominated by tests for cancer. In 2012, the transfer of knowledge of DNA ethylation, circulating nucleic acids and the genetics of diabetes, neurological disorders, psychiatric conditions, cardiovascular diseases, basic immunity and wellness has lead to a number of novel tests. The tables presented in this report illustrate the great variety in molecular tests that have been announced in the past few years. Most of the tests are in development, used for research. However several are now available for use in routine testing, mostly as test services.

Gene sequencing is attracting the attention of medical laboratory professionals. They are beginning to use the technology to study tens and hundreds of genes on a patient specimen, sequence tumors and demystify bacterial genomics.

The technologies used in rapid gene sequencing are being developed and improved by a handful of biotech companies who are racing each other be first to deliver systems to the marketplace that can sequence whole human genomes at a cost of \$1,000 or less. Some innovative medical laboratories are beginning to acquire these sequencing systems and explore how they might be used for clinical pathology laboratory testing.

The past few years have seen the growing importance of commercial test services. All of the major reference labs in N. America and Europe offer a battery of in-house developed and commercial molecular signature assays. There has also been a proliferation of company sponsored lab services.

Molecular assays and lab tests in general hold the key to outcomes research for the new generation of biotherapeutics. These face the threat of poor market penetration unless they can prove to payer groups that they will improve patient outcome and be cost efficient compared to incumbent techniques. The only way to do this is first to show that a gene defect is present and then that the effect of a drug is best proven by a reduction in the physiological element targeted by the drug. Only lab medicine can provide this information. This will become more important as DNA-based diagnostic and therapeutic interventions evolving from the Human Genome Project come to market. Payers are going to cover those therapeutics that prove economically valuable according to rigorous outcomes research.

The market for detecting molecular tests is limited more by their utility than on the technology required to perform these tests. Utility and reimbursement go hand in hand. Almost daily, medical researchers announce their findings linking genes and gene sets to diseases. This has not been translated into many new useful diagnostic tests. For the short term, growth of the market for molecular tests is driven by their potential in drug and medical research and the clinical market segment will increase as the value of nucleic acids as diagnostic markers is developed.







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