Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Vol. VII, No. 8/April 2007

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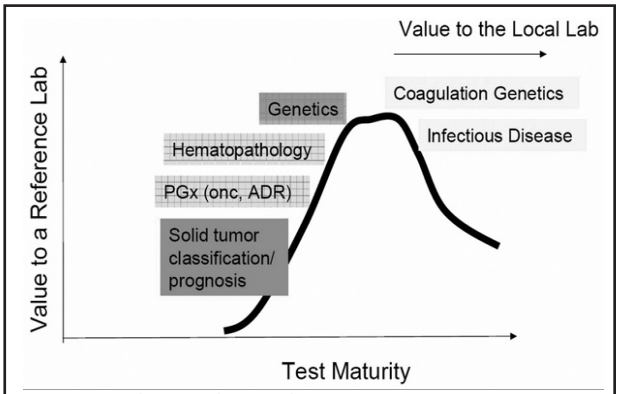
WASHINGTON G-2 REPORTS

Established 1979

Maturing Molecular Diagnostics Good Fit For Local Labs

Just a few years ago, many clinical laboratories were shying away from molecular testing, intimidated by its high complexity and even higher costs, coupled with fears of relatively low volumes. But as molecular testing matures, it is becoming more and more valuable to the full spectrum of clinical laboratories. This theme resonated throughout the presentations of Washington G-2 Reports' second annual molecular diagnostics conference, "Integrating MDx Into Your Lab," held in February in Tampa, Florida.



Source: Noriko Kusukawa, Ph.D., ARUP

"Molecular diagnostics isn't necessarily a collection of esoteric tests, but rather it is a very practical area," said Ronald McGlennen, M.D., president and medical director of Access Genetics. Coagulation genetics and infectious diseases are the two most mature areas of molecular testing, pointed out Noriko Kusukawa, Ph.D., vice president and director of new technology assessment and licensing at ARUP, and therefore, of most value to local (non-reference) labs. These categories are followed by the rapidly maturing areas of genetics, hematopathology, pharmacogenomics, and solid tumor classification and prognosis.

For more about "going molecular," see this month's *Inside the Diagnostic Industry*, pp. 5-7.

Kennedy Introduces Bill to Regulate Lab Tests

On March 2, Senator Ted Kennedy (D-MA) introduced S.736, a bill to provide for the regulation and oversight of laboratory tests. It has been referred to the Senate Committee on Health, Education, Labor, and Pensions, which Kennedy chairs. The bill is co-sponsored by Senator Gordon Smith (R-OR), who chaired last year's hearing by the Special Committee on Aging on a Government Accountability Office (GAO) report that concerned the growing phenomenon of direct-to-consumer genetic tests.

Continued on p. 2

▲ **Bill To Regulate Lab Tests,** *from page 1*

Known as the Laboratory Test Improvement Act, S.736 has the stated goal of ensuring the quality of clinical laboratory tests. In its current form, the bill proposes a number of new regulations. First, it would require laboratory-developed (or "home brew") tests to be labeled with their intended use and regulatory status. The bill states that these requirements would take effect 60 days after the bill's passage.

In addition to the labeling guidelines, the bill proposes mandatory registration of manufacturers and a listing of laboratory-developed tests, as well as adverse advent reporting for laboratory-developed tests. The bill also aims to create a public database of information on laboratory-developed tests, including details on their analytical and clinical validity. FDA would be responsible for this database.

S.736 also proposes a novel scheme for the classification and review of laboratory-developed tests, which under the bill, would generally be categorized as class II devices subject to special controls. This section of the bill creates a new category of test, class III, which would be reserved for tests intended for the diagnosis of a contagious disease or condition likely to result in a fatal outcome, those that would enable the mitigation of the public impact of a disease, or those intended for use in donor screening of particular conditions.

As part of this classification and review process, the bill proposes that the Health & Human Services Secretary issue a rule (first proposed and then final) to establish a specialty area "for laboratory-developed tests to acquire genetic information, including mutations, genotypes, gene expression, and chromosomal structure." The final rule would also include standards for proficiency testing of the lab-developed tests that fall under this specialty area.

The bill ends on an encouraging note. Its penultimate section calls for the development of "a mechanism to provide enhanced reimbursement under federal health programs for in vitro diagnostic products and laboratory-developed tests."

"Our legislation will give health providers and patients the best possible information about the analytical and clinical validity of all clinical tests," said Kennedy in introducing the bill on the floor of the Senate. "It is our responsibility to guarantee such tests are accurate and reliable, and I urge our colleagues to support it."

FDA Clears Quest-Owned Focus Diagnostics' Multiplex HSV Test

The FDA has granted 510k clearance to Focus Diagnostics' Plexus HerpeSelect 1 and 2 IgG test kit, a multiplex, type-specific serology panel for herpes simplex virus (HSV). The test uses Luminex's xMAP platform and is the first in Focus' new line of multiplex infectious disease tests designed to match physician-ordering patterns for diagnosing specific infections.

Cypress, California-based Focus, which Quest Diagnostics acquired last year for $185 million, has made HerpeSelect something of a gold standard in HSV testing. The test has been available in ELISA and immunoblot formats since 2000. Using glycoproteins gG1 and gG2, the HerpeSelect tests enable physicians to detect the presence of antibodies to type 1 and type 2 HSV and to distinguish between them.

CombiMatrix Launches Technical Only Program For Microarray Testing

Some clinical laboratories now have the option of offering clients microarray-based diagnostics without the hassle of actually doing the testing itself, thanks to a program just launched by CombiMatrix Molecular Diagnostics (CMDX; Irvine, CA), a subsidiary of CombiMatrix, which is owned by Acacia Research Corporation. While a technical only option has long been available for more routine genetic testing, this is the first such program for array-based diagnostics.

Geared toward reference labs and other clients, CMDX's bacterial artificial chromosome (BAC) array comparative genomic hybridization (CGH) technical only program (TOP) enables laboratories to outsource the technical, wet-lab component of BAC CGH testing while performing the professional, medical interpretation component in-house. Both components are of course reimbursable, but they are billed separately. Two laboratories have already signed on to the new TOP service: Southwest Genetics Laboratory (San Antonio, TX) and the new molecular diagnostics reference laboratory at the University of Michigan (Ann Arbor, MI).

This novel program will allow laboratories to make use of their licensed medical professionals capable of interpreting complex microarray tests without requiring the substantial capital outlay for equipment, personnel, and training necessary to perform the testing itself. After taking the order and receiving the sample, the client laboratory then sends it to CMDX's CLIA laboratory in Irvine, where the testing is completed. Results are then transmitted electronically to the ordering laboratory, where the medical director interprets the results and bills for the test's professional component.

CMDX President and CEO Mansoor Mohammed says the TOP program "dismantles the 'black-box' image of so many new emerging genomics tests and openly presents the data in a readily interpretable, concise, and transparent manner."

BioView Gets FDA Clearance, Commercialization Rights For Cancer Tests

BioView (Rehovot, Israel), which specializes in lab automation, has received FDA clearance to market its Duet system for automated fluorescent in-situ hybridization (FISH) scanning of breast cancer tissue specimens. The company also recently obtained commercialization rights for lung cancer biomarkers discovered by researchers at MD Anderson Cancer Research Center at the University of Texas.

The FDA clearance allows seven-year-old BioView to market its Duet system, an automated scanning microscope and image analysis system, in the United States for the detection and quantification of chromosome 17 and the HER-2/neu gene using FISH in interphase nuclei from formalin-fixed, paraffin-embedded human breast cancer tissue specimens, probed by the Vysis PathVysion HER-2 DNA Probe Kit. The Duet is to be used as an adjunctive automated enumeration tool, in conjunc-

tion with manual visualization, to assist in the signal ratio of HER-2/neu gene to chromosome 17.

Intended for in vitro diagnostic use, the Duet system can help pathologists detect, classify, and quantify cells of interest based on color, intensity, size, pattern, and shape. BioView has received previous FDA clearances for other applications of the Duet system, including Giemsa staining of hematopoietic cells and amniotic cells stained by FISH using direct labeled DNA probes for chromosomes X, Y, 13, 18, and 21.

An estimated 200,000 new cases of invasive breast cancer occur each year in the United States. Women whose cancers test positive for HER-2/neu are good candidates for treatment with monoclonal antibody immunotherapy with Herceptin (trantuzumab), which targets and blocks the overexpression of HER-2 protein.

The new deal with MD Anderson gives BioView the first crack at a newly discovered set of lung cancer biomarkers. The company first partnered with MD Anderson last year, when it announced an agreement to develop a diagnostic test for early detection of lung cancer in high-risk populations.

Cepheid Buys RT-PCR Test Company Sangtec For $27m

Molecular diagnostics company Cepheid (Sunnyvale, CA) has acquired Sangtec Molecular Diagnostics (Bromma, Sweden), which specializes in real-time PCR (RT-PCR) test kits. Cepheid purchased the company from Altana Pharma, which is part of Nycomed, for approximately $27 million in cash.

Sangtec, which had 2006 revenues of approximately $8 million, has 59 employees. The company is best known for its affigene line of RT-PCR test kits that diagnose such infectious diseases as BK virus, cytomegalovirus, Epstein-Barr virus, Hepatitis B virus, herpes, and varicella zoster virus. Cepheid plan to integrate these kits, which are targeted for managing infections in immunocompromised patients, into its diagnostics portfolio.

Beyond the affigene product line, the acquisition of Sangtec will give Cepheid an R&D team experienced in developing RT-PCR products and an established reagent manufacturing base in Europe.

Genova Diagnostics Buys Reference Lab Specializing In Hormone Testing

Clinical laboratory Genova Diagnostics (Asheville, NC), which focuses on niche testing with specialized test panels, has purchased the operating assets of AAL Reference Laboratories (AAL; Austin, TX), known for its emphasis on hormone testing. The purchase includes testing equipment, clinical test panels, and the customer base of AAL. Terms of the deal were not disclosed.

The Texas company's line of hormone tests include serum-, saliva-, and urine-based tests, which Genova CEO Ted Hull expects to augment Genova's existing product lines in immunology and nutrition testing. Earlier this year, Genova acquired Individual Wellbeing Diagnostic Laboratory (London, England).

Conference Focuses On Integrating Molecular Testing To Address Clinical Needs

In 2006, the rapidly growing molecular diagnostics market was worth about $3.7 billion, with particular growth in infectious disease and cancer diagnosis. Meanwhile, clinical laboratories are simultaneously eager and apprehensive to "go molecular." Therefore, a practical, strategic emphasis characterized the expert-led sessions at "Integrating MDx Into Your Lab," Washington G-2 Reports' second annual molecular diagnostics conference. The message for laboratories looking to add or expand molecular diagnostics capacity? One size does not fit all.

Daniel Farkas, Ph.D.

Conference co-chair Daniel Farkas, Ph.D., executive director of the Center for Molecular Medicine (Grand Rapids, MI) opened the conference with a presentation that examined 10 reasons not to add molecular diagnostics to your lab and then considered 10 rebuttals. Among the widely held assumptions that Farkas challenged about molecular diagnostics were that the equipment is unwieldy, the testing is too expensive and poorly reimbursed, and that none of the tests are FDA-approved.

Also ranking high on Farkas' list of reasons to avoid molecular diagnostics was that the testing was too slow and esoteric. "We used to say that stat molecular testing was impossible," he said, showing a slide of several instruments used for point-of-care molecular testing. Farkas also provided examples of molecular tests that are high-volume and not esoteric, including tests for chlamydia, gonorrhea, HIV, human papilloma virus (HPV), and cystic fibrosis.

A final myth that Farkas helped to dispel was that of the space required to perform and accommodate PCR, which typically requires "pre-" and "post-PCR" areas to minimize contamination. Farkas pointed to real-time quantitative PCR (RT-PCR, not to be confused with reverse transcription PCR), which he called "arguably the biggest development in molecular diagnostics in the last five years." Fast and automated, RT-PCR combines amplification and detection and can be carried out on machines that have a "small footprint." Additionally, "RT-PCR kits don't necessarily require molecular medical technicians," added Farkas.

To In-House or To Send Out?

This was the question posed by Frederick Kiechle, M.D., Ph.D., director of clinical pathology at Memorial Regional Hospital (Hollywood, FL). He began by defining the concept of "losing less money" if an assay is performed in-house instead of sent out to a reference lab. Kiechle provided the example of a quantitative test for hepatitis C. Assuming a volume of 635 tests, he estimated the send-out expenditure at $65,037 versus an in-house cost of $62,528. With an average reimbursement of $28,543, the decision to perform the test in-house saved $2,509.

In-house vs. Send out: HPC Quantitative Test

Volume	635
Send-out expenditure	$65,037
In-house cost	$62,528
Average reimbursement	$28,543
Send-out model loss	$36,494
In-house model loss	$33,985

Source: Frederick Kiechle, M.D., Ph.D.

Selecting a Test Menu

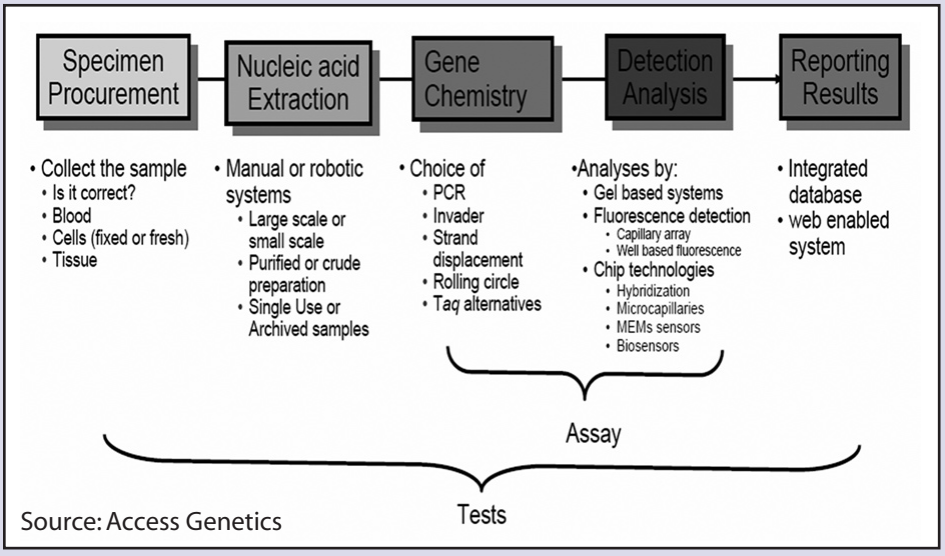
Once you've decided to bring molecular tests in-house, how do you go about choosing a test menu? Ronald McGlennen,

M.D., president and medical director of Access Genetics (Eden Prairie, MN); Cindy Johnson, administrative director of Centracare Laboratories (St. Cloud, MN); and Mark Tulecke, M.D., medical director of Seacoast Pathology (Exeter, NH) outlined the building of a strategic test menu as having four elements: interest and need, IT and infrastructure, testing technology, and assays and tests.

They cautioned against adding a test or assay to the menu as a way to create a need for that test. From a strategic test menu perspective, you determine clinical need—and hence market need—by paying attention to what tests your physicians are requesting. "The agenda is driven by responding to the types of clinical questions that are being asked," said McGlennen.

Johnson agreed. "I can't stress enough the importance of listening when you are setting up a molecular diagnostic program," she said. "Sometimes we don't want to listen to our physicians, but we need to. They don't necessarily understand laboratory testing, but they know what they want in order to make the diagnoses for their patients."

The underlying premise here is was that the old paradigm for the diagnostic laboratory focused almost exclusively on the diagnosis of disease. The new paradigm, as it revolves around molecular diagnostics, is more inclusive of the four aspects of medical diagnostics: evaluating results, identifying risk and symptoms, determining appropriate treatment, as well as diagnosing disease.



Source: Access Genetics

"You propose a strategic menu by assessing what is the best combination of IT services and technical platforms that can address the clinical questions," said McGlennen. "There are many examples of one-box/one-test solutions, but that is not a strategic approach. That's a very expensive approach. When putting together a strategic approach, you want to find a more multiplex capability."

One of the practical approaches in this area is to follow the tissue types. Molecular diagnostic testing is highly versatile because it can be performed on a variety of tissues, as long as DNA or RNA is present; and due to amplification of DNA and RNA, molecular tests are typically viable on very small sample sizes.

"We found by working with small pathology groups, that they often controlled a large proportion of the overall samples selected from patients," said McGlen-

nen. "Do they keep them or send them out? Molecular testing has the ability to use any type of DNA to perform these types of tests. For instance, if you're using liquid Pap, can you use the DNA from this material to do non-obvious tests as well as obvious tests? The answer is an emphatic 'yes.'"

"Molecular diagnostics isn't necessarily a collection of esoteric tests, but rather it is a very practical area," said McGlennen. In discussing HPV testing as an example of strategic test menus, he said, "By bringing those assays in-house, an institution could reduce costs, reduce TAT, and provide an integrated approach to cytology, using molecular techniques."

The conclusion of the panel was that a viable, profitable molecular diagnostics program can be created by developing a strategic test menu built on clinical need, having a robust IT infrastructure, utilizing technology to provide more thorough and useful test results for physicians, and utilizing tissue sources for multiple tests.

Faster, Better, Cheaper?

Like Farkas, Karen Kaul, M.D., Ph.D., emphasized the power of RT-PCR for its ability to provide results more quickly and robustly (that is, quantitatively) and possibly at a lower cost. "The speed of RT-PCR opens new opportunities for testing and positively impacting patient care," said Kaul, director of molecular diagnostics laboratory at Evanston Northwestern Healthcare (ENH; Evanston, IL) and a professor of pathology and urology at Northwestern.

Kaul gave the example of RT-PCR-based molecular testing for bacterial agents such as methicillin-resistant Staphylococcus aureus (MRSA), the primary cause of nosocomial infection. The average MRSA infection costs an estimated $15,000 to treat and is usually diagnosed using culture-based methods that require a liquid culture of blood followed by a Gram stain, plating on solid media, recovery and identification of the bacterial colony, and antibiotic sensitivity testing. Molecular detection of MRSA can be performed on isolated colonies as well as positive liquid culture bottles and primary samples, and results are available in under two hours.

Kaul described a prospective MRSA screening study now underway at ENH that has the goal of reducing MRSA by 25% to 50%. All patients admitted to the hospital are tested for MRSA using RT-PCR-based methods, and those who test positive are isolated and decontaminated. The hospital is now running about 110 tests per day at a rate of two to three runs per day. They have achieved 90% compliance. Their rate of positives is now 8% and declining, says Kaul.

Kaul ended by reflecting upon the number of issues that must be addressed with regard to RT-PCR testing. These issues include the concept of stat testing, round-the-clock lab staffing, the need to decentralize, and the need for random access or single sample capabilities. And while RT-PCR represents a real evolution for clinical molecular diagnostics, Kaul also emphasized the need for further automation to fully realize the power and potential of this technology.

Recordings of all "Integrating MDx Into Your Lab" conference sessions are available for purchase from Washington G-2 Reports. For more information or to place an order, go to www.g2reports.com and click "Recordings" at the top of the page.

3M Launches Medical Diagnostics Business, Buys Acolyte Biomedica

3M (St. Paul, MN) is getting into the diagnostics business. On March 12, the conglomerate announced the launch of a new business unit that will focus on developing and commercializing rapid tests to detect key infectious pathogens. 3M expects to have tests commercially available later this year. In 2006, the company's health care segment generated $4.0 billion, which accounted for 18% of total sales.

The announcement came days after 3M's purchase of Acolyte Biomedica (Salisbury, United Kingdom), maker of an automated platform that aids in the detection, diagnosis, and treatment of infectious diseases. Specific terms of the all-cash deal were not disclosed.

Acolyte's BacLite platform uses adenylate kinase (AK), a ubiquitous housekeeping enzyme that acts as a highly sensitive cell marker. The company has exclusive rights to this technology in clinical microbiology. The automated platform enables culture-based detection of microorganisms directly from clinical specimens.

In Europe, Acolyte has commercialized its rapid assay for methicillin-resistant Staphylococus aureus (MRSA), which occurs frequently in immunocompromised patients. The assay combines traditional microbiological techniques with the AK technology to provide results within five hours.

Formed in 2000, Acolyte had raised VC funding from ANGLE Technology Group and Circus Capital. The company employs 13 specialist scientists and commercial staff at its Salisbury headquarters.

MacroArray Ready To Introduce Non-Invasive Prostate Cancer Test

MacroArray Technologies (Philadelphia, PA) has developed a novel prostate cancer test that relies on the urine-based diagnostic marker known as PCADM-1 (for prostate cancer diagnostic marker 1), a 33 kDa chromosomal protein that is overexpressed in malignant prostate tissue. The marker was discovered by researchers at the Drexel University College of Medicine, with which MacroArray has a licensing agreement. Abbott Laboratories (Abbott Park, IL) will be the first to market the PCADM-1 urine test, after adapting the assay to its own platform.

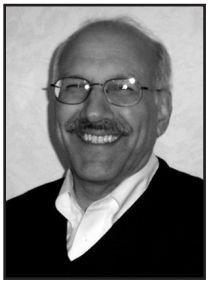
MacroArray hopes that the PCADM-1 test will ultimately replace prostate-specific antigen (PSA) testing. The FDA has approved PSA testing in combination with a digital rectal exam to help detect prostate cancer in men age 50 and older. According to the National Cancer Institute, 70% to 75% of men who have biopsies after PSA tests test negative for prostate cancer. Unlike a PSA test, the PCADM-1 test is non-invasive and easily administered. In a study of 533 patients, the PCADM-1 test had a sensitivity of 79% and specificity of 73% to 100%.

Founded in 2002, privately held MacroArray also has a number of pipeline products, including a urine-based marker for pre-malignant prostate cancer and serum-based markers for colon and prostate cancers. They have also developed oligonucleotide technology to target the prostate cancer tumor gene associated with PCADM-1, and

a therapeutic is now in pre-clinical studies. Investors in the company include Drexel University College of Medicine, Ben Franklin Technology Partners, BioAdvance, and Innovation Philadelphia.

Aureon Laboratories Poised For Growth, Starts With Prostate Cancer Testing

Aureon Laboratories (Yonkers, NY) is betting on the powerful combination of predictive pathology and personalized medicine to advance clinical laboratory medicine. Although founded in 2001, the company is only now ramping up its commercial activity by applying "systems pathology" to develop predictive clinical tests for cancer as well as to facilitate biopharmaceutical research and development.



Vijay Aggarwal, Ph.D.

President and CEO Vijay Aggarwal, Ph.D., believes Aureon is one of several labs leading the way in bringing practical personalized medicine to the clinical laboratory industry. "Aureon is one of the companies that is evolving in diagnostics that are focusing on personalized medicine and attempting to create tools that allow patients and physicians to make better therapeutic choices and more personalized care management based on the characterization of their individual disease," says Aggarwal.

Aureon was founded in 2001 by three molecular pathologists: Carlos Cordon-Cardo, M.D., Ph.D. from Memorial Sloan-Kettering Cancer Center; José Costa, M.D., from the Yale School of Medicine; and Robert Singer, Ph.D. from the Albert Einstein College of Medicine. The company operates as a CLIA-certified reference laboratory and has been approved for work in New York state. The laboratory also recently passed a CAP inspection and joined the American Clinical Laboratory Association.

Proprietary technology underlies Aureon's diagnostics work. According to Aggarwal, the company's first four years were spent developing tools that rely on computer image analysis of tissue samples, tools that rely on simultaneous measurements of proteins in paraffin-embedded tissue, and tools that enable localization of protein expression within particular cells and subcellular compartments.

In the last two years, Aureon has applied those tools to a number of tissue types and tumor types. The primary focus has been on prostate cancer prognosis. Aureon's initial test was designed to predict outcomes and guide treatments in patients who have had their prostates surgically removed. The company is now in the final stages of developing a test, using the same technology, but now applying it to prostate needle biopsy, Aggarwal tells *DTTR*. This allows predictions of outcomes for prostate cancer patients at the point of diagnosis. Aureon plans to conduct additional validation studies this year.

Prostate Px, Aureon's lead product, bills for $1,968. Reimbursement for the test, which can predict the likelihood of prostate cancer recurring after surgery, is a complicated issue that is still being resolved. "We have received payment from most of the carriers we've submitted claims to," says Aggarwal. "And we continue to work proactively with third-party insurers to gain adequate reimbursement."

In addition to prostate cancer, Aureon has been working on applying its technology to non-small cell lung cancer, breast cancer, and liver toxicology. "We've in-licensed technology to detect nascent RNA in paraffin embedded tissue," notes Aggarwal. "And we have also in-licensed technology that relies on measuring mutational frequency at the genomic level that's useful for early cancer detection."

In August 2005, Aureon closed on a Series B venture capital financing round totaling $20 million. The funds were used primarily to expand its sales force and concentrate on commercialization of the diagnostics laboratory.

"Our particular focus is pathology based," says Aggarwal. "We believe pathology is a central science in the diagnosis of disease, especially cancer, and also an essential science in the staging of disease. But we also think that modern-day proteomics and genomics and computational biology will allow us to be more quantitative in doing that. We've applied those modern technologies to pathology to try to improve its level of quantitation and objectivity."

NeoGenomics Expands With West Coast Lab

NeoGenomics (Fort Myers, FL) has received CLIA certification for its new laboratory in Irvine, California. This is the third laboratory for the molecular testing company, which also has a laboratory in Nashville, Tennessee.

Specializing in molecular diagnostics for cancer, NeoGenomics performs cytogenetic analysis, fluorescence in-situ hybridization (FISH), flow cytometry, morphology studies, anatomic pathology, and molecular genetic testing. The company is seeking to increase its average revenue per oncology case with additional complementary testing platforms and focused marketing to larger oncology and hospital groups.

In a service that targets pathologists, NeoGenomics offers what it calls Genetic Pathology Solutions (GPS), an algorithm-driven process that combines flow cytometry, FISH, cytogenetics, and molecular assays into a single summary report. From an initial diagnostic evaluation, additional testing is automatically triggered, and test cancellations are issued based on medical necessity. The company believes that GPS results in faster diagnosis, fewer test add-ons, and a higher level of patient care.

Founded in 2001, NeoGenomics has been successful in growing not only the number of requisitions received and the number of tests performed, but also the average number of tests per requisition, which is up to 1.37 in FY 2005 compared to 1.01 in FY 2004, when it mostly performed only cytogenetic testing. In FY 2005, the last year for which full-year financials are available, the company earned total testing revenue of $1.9 million, up a whopping 238% over FY 2004. Average revenue per requisition increased 29%, to $632.23 in 2005, compared to $489.97 in FY 2004.

For the 2007 fiscal year, the company forecasts revenue of $14 million to $16 million, maintaining gross margins of approximately 55%, net income in the range of $1.3 million to $1.7 million, and capital expenditures of approximately $1 million to $1.5 million.

IVD Stocks Drop 4%; Bio-Rad Slumps; Clinical Data Jumps

The 24 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 4% in the four weeks ended March 9, with six stocks up in price and 18 down. Year to date, the G-2 Index is up 2%, while the S&P 500 Index is down 1% and the Nasdaq is off 2%.

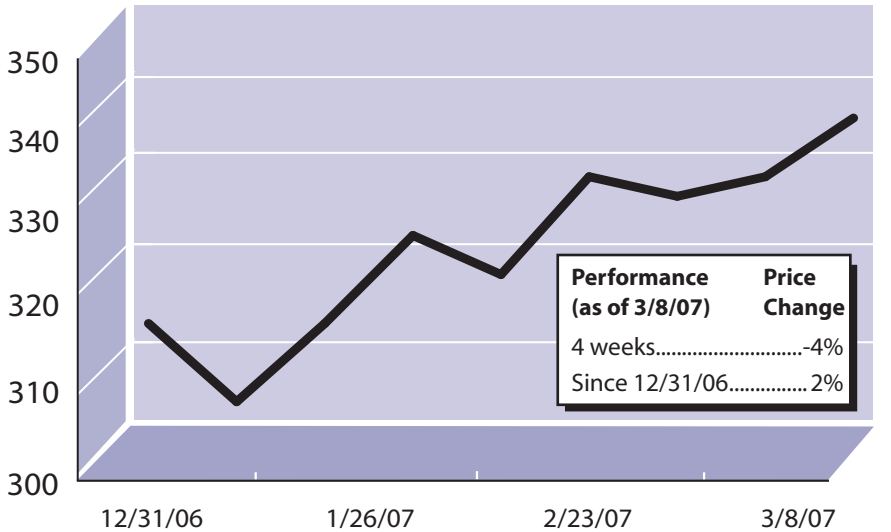
Bio-Rad Laboratories (Hercules, CA) fell 20%, to $68.94 per share for a market cap of $1.8 billion. The company's fourth quarter revenue of $343.1 million was up 11.6% compared to the same quarter for the previous year, with quarterly net income of $16.6 million, or 61 cents per diluted share. Although both numbers exceeded analyst expectations, the stock took a hit in the wake of the earnings call on the company's statement that factors such as increased competition were likely to erode operating earnings for 2007.

Things were looking up at **Clinical Data** (Newton, MA), a 2007 addition to the G-2 Index. Shares in the IVD company were up 24%, to $22.25 per share for a market cap of $206 million. The company recently reported results for the third quarter. Revenue for the three-month period increased 19.9%, to $22.0 million, compared to $18.4 million for the same period a year ago.

Clinical Data's Cogenics division, which provides pharmacogenomics and molecular biology services, recently announced that it will boost throughput and capacity with the Radius automation platform, which is manufactured by Protedyne.

Like Bio-Rad, **Quidel** recently posted strong earnings yet is suffering the repercussions of wavering analyst confidence. Shares were down 19%, to $10.79 each in the wake of one analyst's downgrade based on the company's unexpected guidance of a 40% tax rate for 2007, which hampers the ability to estimate price-earnings valuations.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 24 IVD companies.

Up	Price	% Chg
Abaxis	$22.37	4%
Abbott Labs	54.39	4
Biosite	53.86	1
Clinical Data	22.25	24
Cytyc	32.55	10
Stratagene	8.65	7
Down		
Affymetrix	25.63	-8
Beckman Coulter	64.79	-1
Becton Dickinson	75.00	-3
Bio-Rad	68.94	-20
Cholestech	16.11	-8
Dade	41.59	-4
Immucor	28.92	-11
Digene	41.74	-17
Gen-Probe	48.32	-6
Inverness Medical	42.03	-1
Johnson & Johnson	62.14	-5
Luminex	14.17	-11
Meridian	27.89	-4
Nanogen	1.34	-11
OraSure	7.46	-8
Quidel	10.79	-19
Third Wave	5.22	-2
Ventana	40.86	-3

G-2 Insider

Legal Battle Over HPV Testing IP Continues . . . The latest parry in the legal battle for intellectual property related to human papilloma virus (HPV) testing is that of Third Wave (Madison, WI), which was sued by Digene (Gaithersburg, MD) for patent infringement earlier this year. Third Wave plans to commercialize a HPV test that will be a direct competitor to that of Digene, which now markets the only FDA-approved test for the virus, which is the primary cause of cervical cancer. Third Wave currently sells analyte-specific reagents for HPV.

Filed in early March, Third Wave's countersuit includes allegations that Digene has abused its monopoly power to thwart competition in the HPV diagnostic marketplace. An early 2008 trial date is expected.

In January, Digene sued Third Wave for patent infringement relating to HPV type 52, which accounts for 0.5% of HPV-positive specimens in the United States, according to Digene's package insert. Among the remedies Digene sought were preliminary and permanent injunction preventing further patent infringement, a declaration that the patent in question is a valid and enforceable patent infringed on by Third Wave, and compensatory damages.

This is not the first courtroom tussle for Digene and Third Wave. In October 2005, Third Wave filed suit against Digene seeking a declaratory judgment supporting Third Wave's right to sell its HPV products. In January of last year, the two companies reached an agreement by which the suit was dismissed without prejudice and also agreed not to bring HPV-related suits against one another for a year.

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CombiMatrix 949-753-0624
Digene 301-944-7000
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Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Web site: www.g2reports.com.

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