# Diagnostic Testing and Technology Report

**Competitive Intelligence & Analysis for an Expanding Global Market**



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CONTENTS




WASHINGTON G-2 REPORTS

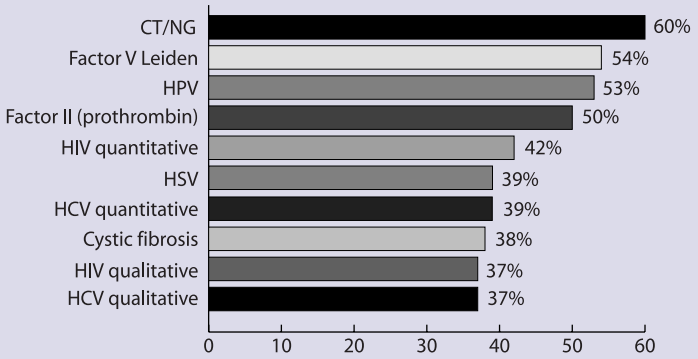
**Established 1979**


## G-2 Survey Reveals Top 10 Molecular Tests

Washington G-2 Reports asked 110 hospital and independent laboratories that perform molecular testing which tests they currently offer, which ones they plan to add, and which ones they have no plans to offer. Among the survey's results is a revealing top 10 list that finds at least 50% of the labs surveyed performing tests for Chlamydia/gonorrhea (CT/NG), Factor V Leiden, human papilloma virus (HPV), and Factor II (prothrombin).

Over one-third of the labs offer tests for HIV, hepatitis C (HCV), or cystic fibrosis. In the cases of HCV and HIV, where both a quantitative and qualitative assays are available, the quantitative version of the test narrowly edged out the qualitative.

**Top 10 Molecular Tests Currently Offered**




Source: Washington G-2 Reports 2006 Molecular Diagnostics Survey, n=110


➥ *p. 2*


## FDA To Extend Comment Period On ASR, IVDMIA Draft Guidance

The FDA will extend the public comment period on recently issued draft guidance concerning analyte-specific reagents (ASRs) and the newly created grouping of tests known as in vitro diagnostic multivariate index assays (IVDMIAs), *DTTR* has learned.

The agency's current plan is to extend the public comment period by an additional month, which would keep it open until January 5. "Many of the stakeholders have said that they need time to react to the guidance and get their comments together," said Janet Woodcock, M.D., the FDA's deputy commissioner for operations. "If there remains a lack of clarity, we may hold additional discussions. We really want to develop a clear and workable policy in this area….We want to make this work."


➥ *p. 2*

▲ **Top 10 Molecular Tests,** *from page 1*

Molecular-based tests for sexually transmitted diseases, particularly CT/NG, were some of the earliest tests to be brought on by many labs because of the high volumes. As a result, 60% of laboratories surveyed indicate they currently offer CT/NG, with another 10% indicating they have plans to offer molecular CT/NG tests in the next one to five years.

HPV testing is also currently being offered by 53% of surveyed laboratories, with 22% planning to bring it on in the next five years. HIV quantitative is being handled by 42% of labs and HIV qualitative by 37%. Approximately 25% of laboratories expect to bring on HIV quantitative and/or HIV qualitative in the next five years.

Testing for coagulation mutations, Factor II (prothrombin) and Factor V Leiden, have also been quick to be adopted by laboratories due to high demand. More than half (54%) of laboratories surveyed said they already offered Factor II (prothrombin), with an additional 23% indicating they expected to bring it on in the next five years. Factor V Leiden is currently offered by 54% of survey respondents, with 21% indicating they expected to bring the test on board in the next five years.

Cystic fibrosis testing is currently handled by about a third (38%) of surveyed laboratories, with 30% indicating they expected to bring this test on in the next five years.

A high percentage of laboratories indicate that they do not have plans to offer Cyp450 (42%), HLA-typing (67%), HER-2/neu (36%), UGT1A1 (57%), and prenatal (chromosome 13, 18, 21, X, Y) (61%) testing. Although HLA-typing is typically the domain of a flow cytometry laboratory, and HER-2/neu and prenatal testing are typically handled by cytogenetics laboratories, the relatively low interest in Cyp450 is somewhat of a puzzle, given the amount of media attention personalized medicine receives. However, despite that, 33% say they do have plans to add Cyp450 in the next three to five years. This test or series of tests may be too new for laboratories to be actively considering adoption, or there may as yet be difficulties in interpretation, as well as in demand. If physicians feel the Cyp450 results will limit treatment options rather than fine tune treatment options, they may be slow to require them.

▲ **ASR, IVDMIA Draft Guidance,** *from page 1*

The two distinct draft guidance documents aim firstly, to better explain the ASR Rule, issued in 1997, and secondly, to define a new area of complex testing that the agency believes should require FDA clearance. Woodcock described the ASR Q&A Guidance as "simply interpreting and explaining the [ASR] rule that was already put into effect. It's not making new regulations or new distinctions."

In the wake of the 1997 publication of the ASR rule, which was intended to create a safe harbor for laboratory-developed tests while assuring the quality of the reagents they contained, there was inadvertent or deliberate abuse of the definition of an ASR. For example, manufacturers sold kits disguised as ASRs to avoid FDA oversight.

The second draft guidance defines a new testing category: IVDMIAs. These are tests that use complex mathematical formulas to interpret large amounts of gene and protein data to produce results that guide medical decision making. "We think [IVDMIAs] are different in substantive ways from in-house developed tests that we've seen in the past and that we're exercising enforcement discretion over," says

Woodcock. The FDA believes these tests should require clearance, and most of them will likely be subject to class II and III special controls.

For more on the FDA's draft guidance and its implications, see next month's issue of *DTTR* and watch for breaking news related to this issue on the Washington G-2 Reports Web site, **www.g2reports.com**.

## New Reference Lab Sees Panacea In Pharmacogenomics

New CLIA-certified laboratory Panacea Laboratories (Gaithersburg, MD), a division of Panacea Pharmaceuticals, has launched its first test, a pharmacogenomic assay called TK Sense. The test uses RT-PCR to measure expression of the gene encoding human aspartyl beta-hydroxylase (HAAH) in the leukocytes of patients with chronic myelogenous leukemia (CML) to identify those patients unlikely to respond to treatment with imatinib mesylate, known by the trade name Gleevec. List price for the test is $500.

Gleevec, which is recognized as the most effective nontransplant treatment for CML, costs about $35,000 per year. "Identifying patients with a low likelihood of responding to Gleevec may avoid potentially serious adverse effects, hasten the initiation of potentially more beneficial treatment, and save considerable costs," says Stephen Keith, M.D., president and chief operating officer of Panacea Pharmaceuticals.

Expression of the gene encoding HAAH significantly decreases when the leukocytes of CML patients are cultured in the presence of Gleevec, so the TK Sense test compares HAAH gene expression following culture in the presence of Gleevec with expression in the absence of the drug. Test results are reported as a percentage decrease in gene expression. A decrease in HAAH gene expression level correlates with drug response. Nonresponders to Gleevec treatment do not show a decrease in HAAH expression in the assay.

Next up for Panacea are serum HAAH tests to diagnose and monitor prostate, liver, lung, and cervical cancer. The first of these tests should be available early next year. Additionally, the company is developing HAAH gene expression tests to monitor minimum residual disease (MRD) in patients following treatment for various leukemias. Also in the works are antibodies directed against HAAH as novel agents for the treatment of cancer.

## Qiagen Acquires Genaco For PCR Multiplexing Technology

Qiagen (Venlo, The Netherlands), a provider of molecular diagnostics products and solutions for preanalytical sample preparation, has acquired all outstanding shares of Genaco Biomedical Products (Genaco; Huntsville, AL) for $22 million in cash and 125,000 shares of preferred Qiagen stock. Qiagen will also pay up to $18 million based on the achievement of certain milestones. Genaco is an early-stage company applying a proprietary PCR-based multiplexing technology, Tem-PCR, to develop Templex molecular diagnostic tests. Qiagen expects this acquisition to contribute approximately $200,000 in sales in the last quarter of 2006 and approximately $3 million in sales for the full year of 2007.

Multiplex assays screen for multiple targets in a single test. Tests of this type are widely adopted in genetic and human leukocyte antigen (HLA) testing. Newer testing applications include viral and bacterial panels, nosocomial infections, and bacterial drug resistance mutations.

Genaco's Tem-PCR technology employs a combination of so-called nested- and super-primers. The technology is optimized and marketed for use on the Luminex platform, which Qiagen has been selling since 2000.

Depending on the number of markers present in a sample, Genaco's Templex products provide a qualitative and a semi-quantitative result, which will complement Qiagen's large portfolio of qPCR-based molecular diagnostic assays. Among Genaco's research use only (RUO) products are ResPlex III, a multiplex panel that can differentiate among eight influenza subtypes, and StaphPlex for bacterial infections. The company is now completing clinical studies and plans to submit a 510k application to the FDA for its H5N1 avian flu assay, a subset of its ResPlex III panel product.

## Orion Teams Up With Mayo To Validate Breast Cancer Screening Test

*Approximately 211,000 new cases of invasive breast cancer are expected in the United States in 2006, according to American Cancer Society estimates.*

Orion Genomics (St. Louis, MO) is collaborating with Mayo Clinic (Rochester, MN) to study the clinical utility of Orion's breast cancer screening tests, which are based on epigenetic biomarkers that were discovered using DNA methylation technologies. Mayo and Orion will validate the tumor specificity of Orion's breast cancer biomarkers by analyzing their cross reactivity in more than a dozen additional cancer types.

Orion is using epigenetic markers to develop cancer screening tests that are designed to work in blood, tissues, and other biological samples for the early detection of breast, lung, ovarian, and colon cancers. MethylScope, the company's biomarker discovery platform, can quantitatively detect the methylation status of all human genes on a single array. Novel biomarkers associated with specific diseases are discovered by comparing methylation profiles. To date, Orion has discovered and validated over 50 novel breast cancer biomarkers.

## Innogenetics Options AdnaGen's Technology For Prenatal Testing

Innogenetics (Brussels, Belgium) has entered into an exclusive option and evaluation agreement with AdnaGen (Langenhagen, Germany) for a technology that selectively and specifically isolates fetal red blood cells circulating in maternal blood. This technology could make possible DNA testing on fetal red blood cells through a blood sample taken from the mother, making it an appealing alternative to such invasive techniques as chorion biopsy and amniocentesis. Such a test could also be carried out at an earlier stage of pregnancy than is currently the case for amniocentesis.

AdnaGen's technology uses monoclonal antibodies to specifically and selectively isolate fetal red blood cells, circulating in minute amounts, from maternal blood. Current techniques for the enrichment of fetal red blood cells from maternal blood have proven to be laborious and lacking in selectivity, specificity, or both.

"The agreement between AdnaGen and Innogenetics will provide the most efficient way to progress from a highly specific reagent to isolate and/or detect fetal cells in maternal blood to a routine-use assay," said Winfried Albert, COO and CSO of AdnaGen.

# Cracking The Code: The Lowdown On Molecular Diagnostics Coding

Joan Logue

New molecular tests are developed every day, and some of the systems originally developed for more traditional diagnostics are having trouble keeping up. Many labs complain that coding for a molecular assay can be more complex than the assay itself. In the hopes of getting some insight into this issue, *DTTR* talked with Joan Logue, a principal with Health Systems Concepts (Longwood, FL), a national consulting firm for clinical laboratory Medicare coding and billing compliance and Medicare regulations:

***What advice do you have for those who might be new to coding for molecular tests?***

The most difficult area to code for is human genetic testing. The codes can be somewhat ambiguous, which can lead to multiple interpretations of their correct use. Coding in this area requires knowledge of the CPT coding rules, understanding of the current CCI edits, and an understanding of the steps in the assay, why they were performed, and whether the step is codable.

***What are some of the most common pitfalls people encounter or errors they make when coding for molecular tests?***

Firstly, not considering the intent of the code. For example, when code 83907 *Molecular diagnostics; lysis of cells prior to nucleic acid extraction (e.g., stool specimens, paraffin-embedded tissue)* was added to CPT in 2006, many labs began billing this code incorrectly. The intent of the code was that it should be used when a separate procedure is required prior to the isolation or extraction of nucleic acid. The examples listed in the code description define types of specimens that require a significant amount of extra preparation prior to the nucleic acid extraction.

## Molecular Codes

- ❑ Some with Chemistry CPT codes (83XXX), some in Microbiology (87XXX) to include cytogenetics
- ❑ Intended for analysis of nucleic acid
- ❑ An appropriate code is used for each portion of an assay, rather than a single code for the entire assay of one analyte (except infectious agents and cytogenetics)
- ❑ Local variations in payment rates depending on Medicare carrier

Source: Jeffrey A. Kant, Ph.D., University of Pittsburgh Medical Center

A second pitfall is not carefully considering the description. If the code does not have the word "each" in the description, the laboratory may not report units for the code.

Another problem is not understanding the purpose of the step. For example, code 83894 *Molecular diagnostics; separation by gel electrophoresis (e.g., agarose, polyacrylamide)* or code 83789 *Spectrophotometry, analyte not elsewhere specified* should not be billed if the purpose of the step is to verify sufficient DNA for the test. This is a nonbillable quality control step.

***Many of the code changes and additions for the 2007 Clinical Laboratory Fee Schedule will affect those who perform molecular testing. What are those key changes or additions?***

CPT has added one new code to the molecular diagnostic codes, 83890 through 83914 located in the chemistry section. The new code, 83913 *Molecular diagnos-*

*tics*; *RNA stabilization*, allows the laboratory to bill for this procedure when a special tube or kit is used to stabilize the RNA in the sample prior to testing. The 2007 Medicare clinical laboratory fee schedule National Limitation Amount (NLA) for 83913 will be $18.66.

**Tips For Molecular Diagnostics Coding**

- ❑ Code separately for each procedure in the analysis
- ❑ Correct coding requires an understanding of the method
- ❑ Code precisely and consider the description of the code
- ❑ Coding compliance essential for the referring lab and testing lab
- ❑ MUEs are expected to address the number of units reported for molecular testing

There are also four new codes added to the molecular infectious agent subsection in the Microbiology section of CPT. These codes are:

87498 *Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique*

87640 *Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique*

87641 *Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique*

87653 *Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique*

The four new infectious agent codes all have an NLA of $49.04.

Also, CPT added an important parenthetical to this section that clarifies when to use the molecular infectious agent codes and how to code when a code is not listed for a specific infectious agent. The parenthetical states:

> *(For each specific organism nucleic acid detection from a primary source, see 87470-87660. For detection of specific infectious agents not otherwise specified, see 87797, 87798, or 87799 one time for each agent.)*

Prior to this clarification, kits that resulted in multiple organisms had to be billed using codes 87800 or 87801, the multiple organisms' codes. The problem with using these codes is that they are priced at the two organisms detection level. This meant when the laboratory used a kit that detected and resulted in more than two organisms, it was only being paid for two. Now, with this clarification, the laboratories will be paid for each organism resulted.

This parenthetical does not apply to kits that test for multiple organisms but simply gives a yes/no answer and requires further testing to identify the specific organism present.

***Will Medicare reimburse for ASR-based molecular tests? How are these coded for?***

CMS has left the coverage decision for non-FDA approved, in-house laboratory

tests (home brews) to the local Medicare contractor. Presently, the majority of Medicare payers cover in-house laboratory tests (using analyte specific reagents). Once the regional contractors are in place, there may be much more uniform coverage decisions amongst the payers.

For human genetic testing, the coded steps must be provided with the test's standard operating procedure (SOP) to correctly code the in-house laboratory test. Without the SOP, the coder has no knowledge of the codable steps in the procedure.

For infectious agent in-house developed tests, the laboratory would code using the specific infectious agent code, if available. If a specific code is not available, the coder would use the appropriate "not otherwise specified" code.

***And finally, you have seen how coding for molecular tests has evolved over the years. What trends are you seeing in CMS's handling of the molecular area in terms of coding? Any predictions as to what changes we might see in the coming years?***

The molecular code sections for human genetic testing and for the infectious agents were first revised in 1993 and updated throughout the following years. Between 1993 and now, CMS's primary focus through the CCI edits was on laboratories not billing 83912 *Molecular diagnostics; interpretation and report* with the infectious agent codes.

**Key Coding Questions**

- ❑ Is it a quality control (QC) step?
- ❑ Is the assay simplex or multiplex?
- ❑ Does it really fit?
- ❑ Is it codable?
- ❑ Is it diagnostic or confirmatory?
- ❑ Did the reaction occur?
- ❑ Is the code applicable?
- ❑ Is the assay billable to government payers?

At the local level, very few contractors have local policy determinations for the molecular codes. However, both at the national and local level, this may be changing. It is possible that CMS will use the new Medically Unlikely Edits (MUEs) table, which will be updated each quarter starting in 2007, as a tool to limit the units for molecular codes for both clinical laboratory and pathology.

In addition, in 2006, no Medicare carrier that I know of covered the microarray code 88384 *Array-based evaluation of multiple molecular probes; 11 through 50 probes*. The 2007 proposed Physician Fee Schedule has again left the coverage of this code up to the local contractor.

At the local level, we may also see some limitations put in place and, as the regional contractors are put in place, we may see even further restrictions. Apparently it is being discussed within Trailblazer, one of Medicare's largest carriers, not to cover any of the microarray codes in the pathology section. I understand that the professional associations are aware of this and are taking steps to provide Trailblazer with information on the diagnostic value of arrays.

*Correction:* The 2005 revenue of LabCorp was inaccurately stated in the November 2006 issue of *DTTR* ('Inside the Diagnostics Industry,' p. 5). The correct figure for the company's annual revenue in 2005 is $3,327.6 million. *DTTR* regrets the error.

# Specialty Labs Launches First Genomic Liver Test For HCV Patients

Specialty Laboratories (Valencia, CA), the esoteric testing division of AmeriPath (Palm Beach Gardens, FL), has launched HCV Liver Fibrosis GenotypR, the first genomic clinical test to predict progression to liver fibrosis or cirrhosis for hepatitis C virus (HCV) patients.

This test identifies the patient's genomic signature of seven single nucleotide polymorphisms (SNPs) that combined with gender provides a Cirrhosis Risk Score (CRS) correlating with relative risk of progression to liver fibrosis or cirrhosis. It can identify which HCV patients are at reduced risk of progression to fibrosis as well as those with up to a four-fold increased risk compared to low-risk patients. List price for the test is $554, a company representative tells *DTTR*.

### HCV Liver Fibrosis GenotypR

***Sample:*** Whole blood

***Method:*** Multiplex PCR and multiplex Allele Specific Primer Extension with a universal tag sorting system

***Platform:*** Luminex 100 X MAP

***Turnaround Time:*** 2 days

***CPT codes:*** 83891, 83892X2, 83898, 83909, 83914X8, 83912

***List price:*** $554

Source: Specialty Laboratories

HCV affects approximately four million people in the United States and is a major cause of chronic liver disease. Liver biopsy is the primary method of establishing which patients to treat, based upon the amount of bridging fibrosis present at the time of the biopsy. Complications of chronic HCV infection are the leading indication for liver transplantation.

# ARUP To Develop Pharmacogenomic Cancer Test Using Saladax's ASRs

Reference lab giant ARUP Laboratories (Salt Lake City, UT) is embracing pharmacogenomics with plans for a new test that will enable oncologists to personalize dosing of busulfan, a chemotherapeutic agent sold under the trade names Busulfex and Myleran. The company has entered into a licensing agreement with Saladax Biomedical (Bethlehem, PA) for the two-year-old diagnostic firm's novel antibodies against busulfan and for other raw materials that ARUP will use to develop a microtiter plate assay to measure the concentrations of busulfan in the bloodstream of patients undergoing allogeneic hematopoeitic stem cell transplant for chronic myelogenous leukemia. Over 60,000 such transplants are performed each year.

ARUP would be the first reference laboratory in the world to offer a busulfan blood level monitoring test based upon antibodies. The test would improve upon current tests, which use physical methods such as high performance liquid chro-

matography (HPLC), by enabling faster results. The long turnaround times of currently available tests often mean that results come too late to adjust dose and reduce toxic side effects of busulfan treatment.

Founded in 2004 by Roche veterans Salvatore Salamone, Ph.D., and Adrienne Choma, Saladax is developing a line of 11 "personalized chemotherapy management" assays for the most common anti-cancer drugs. The company plans to distribute these tests through strategic collaborations with IVD industry partners and laboratories such as ARUP.

## Third Wave Sees Growth For ASRs, Plans FDA Submissions

*FDA clearances for its HPV tests will give Third Wave a much bigger share of the $150 million global HPV market, which is growing at more than 20% annually.*

Third Wave Technologies (Madison, WI) is on track with its plans to submit for FDA clearance molecular tests based upon products it now sells as analyte-specific reagents (ASRs), management confirmed recently. The products include a test to aid in warfarin (Coumadin) dosing as well as assays for cystic fibrosis (CF), human papilloma virus (HPV), and Chlamydia/gonorrhea (CT/NG).

Third Wave is best known for its Invader platform chemistry, scalable DNA and RNA analysis chemistry that can be run on standard thermal cyclers and plate readers. By the end of this year, the company will seek FDA clearance for its CF ASR, CFTR InPlex, which has enabled many labs to bring CF testing in-house.

In July, the company began clinical trials for its two HPV products: a screening test to detect the presence of 14 high-risk types of HPV and a genotyping test to detect HPV 16 and HPV 18, the types of HSV that cause approximately 70% of cervical cancer cases. The trials are on schedule, and FDA submissions are expected next year.

FDA clearances for its HPV tests would give Third Wave a much bigger share of the $150 million global HPV market, which is growing at more than 20% annually. Meanwhile, penetration of the company's HPV ASRs is growing steadily. In the third quarter, the company gained three new HPV customers, bringing the total to 10. Third Wave currently has a base of 160 clinical lab customers in the United States.

Third Wave is also planning to enter another high-volume molecular testing category: CT/NG, which has a global market of more than $200 million. "We remain on track to deliver [CT/NG] ASRs to the market during the first half of 2007 and expect to make a submission to the FDA during the second half of the year," said Conroy.

Bristol-Meyers's recent announcement that it will add a "black box" warning to the Coumadin label is more good news for Third Wave. The company's recently released research use only (RUO) warfarin product is being used by 25 customers. The Invader Coumadin Companion Molecular Assay IVD will be submitted to the FDA as soon as the relabeling of the drug is completed. Conroy estimates that there are more than one million testing opportunities for this product in the mar-

ket. "Strategically, this could be a potential big testing market moving into the future," he said. "The challenge is going to be physician education, and we are working hard to develop strategies to impact physician education without massive marketing dollars."

## IVD Industry Movers And Shakers

Molecular diagnostics service company **Access Genetics** (Eden Prairie, MN) has named a new chief executive officer: **George M. Hoedeman**, whose recent roles include CEO of South Bay Medical, president of the automation technology division of Mentor Corp., chairman of Wound Care Technologies, and CEO of MicroVision.

As CEO, Hoedeman will focus on developing Access Genetics' Web-based molecular diagnostic services, a model that currently serves about 35 hospital laboratories, reference laboratories, and private pathology groups nationwide.

**James Godsey, Ph.D.**, has joined **Digene** (Gaithersburg, MD) as senior vice president of research and development. Godsey was formerly vice president of research and development for Veridex, a Johnson & Johnson cancer diagnostics company. **Attila Lorincz, Ph.D.**, will continue as Digene's chief scientific officer and assume the new position of senior vice president, science and technology.

**AmeriPath** (Palm Beach Gardens, FL) is expanding its GI diagnostic services in New England with the appointment of **Mark Redston, M.D.**, as director. In addition to servicing the needs of gastroenterologists in the Northeast region, Reston will provide leadership and molecular expertise in the application of new molecular diagnostic tests focused on GI disease.

**David Sidransky, M.D.** was named a board member of **Zila** (Phoenix, AZ), a cancer diagnostic company. Sidransky is the director of the head and neck cancer research division at Johns Hopkins University School of Medicine. He succeeds resigning board member Mike Lesser, the president of Dental Concepts.

Former Roche Molecular Systems CEO **Heiner Dreismann, Ph.D.**, has joined the board of directors of **GeneNews** (Toronto, Canada), the molecular diagnostics company formerly known as **ChondroGene**. The company plans to tap Dreismann's experience as it moves toward commercialization of its blood-based molecular diagnostic tests.

**John Ryan, M.D., Ph.D.**, chief medical officer of AVEO Pharmaceuticals, **Richard Hockett, M.D.**, medical fellow and director of genomic medicine at Eli Lilly & Co., and **Buzz Sztukowski**, senior vice president, global marketing and strategic development at bioMerieux have joined the scientific board of **Expression Analysis** (Durham, NC). The additions are expected to assist the company, which provides microarray testing, analysis, and data management, in bridging the use of microarray-based pharmacogenomic assays in clinical trials to targeted molecular diagnostics.

# IVD Stocks Rise 4%; Cholestech Climbs 29%

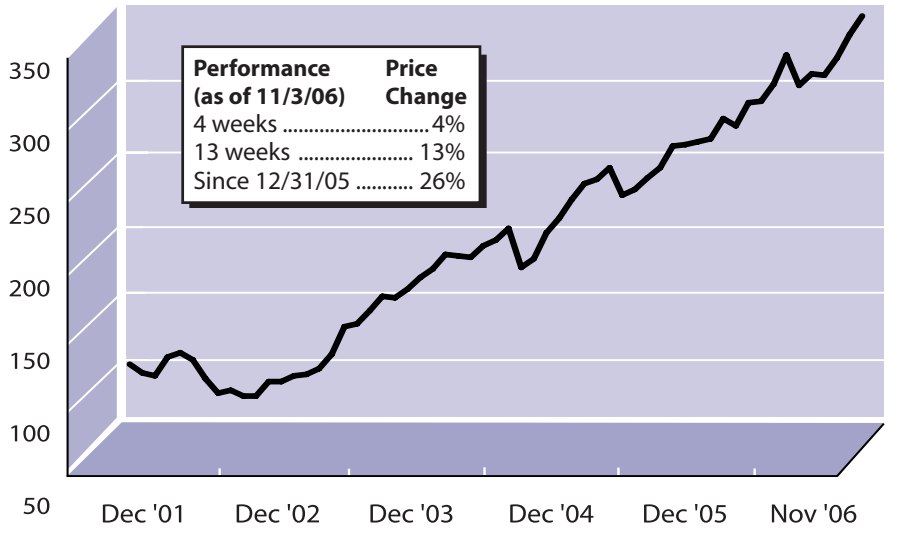
The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 4% in the four weeks ended November 3, with 14 stocks up in price, one unchanged, and six down. Year to date, the G-2 Index is up a whopping 26%, while the S&P 500 Index is up 9% and the Nasdaq has gained 6%.

**Cholestech** (Hayward, CA) jumped 29% to $16.09 per share for a market cap of $260 million. The maker of point-of-care diagnostics recently announced that strong sales for the most recent quarter had increased profits by 38%. Revenue for the quarter rose 12% to $17.2 million, compared to the previous year's $15.3 million. Cholestech also announced a three-year agreement with privately held Life Line Screening (Cleveland, OH), a mobile preventative testing company that will use the Cholestech LDX point-of-care testing system in the 85 vans serving 1.4 million Americans each year.

Things were also looking up at ever-volatile **Affymetrix** (Santa Clara, CA). Shares in the microarray giant were up 24% to $25.82 per share for a market cap of $1.77 billion. Although the company reported a $14.2 million loss for the third quarter due to higher costs, the stock climbed on the higher than expected revenue numbers. Quarterly revenue of $84.7 million beat the analysis consensus of $80.9 million and the $83.4 million that the company posted during the same period last year. Affy attributed $4.6 million in revenue to **Perlegen Sciences** (Mountain View, CA), its pharmacogenomics spin-off.

Affy also recently teamed up with **Iconix** (Mountain View, CA) to launch ToxFX, a toxicogenomics research tool that can help scientists to prioritize drug candidates and make preclinical development decisions more quickly. The system makes it possible to obtain a full compound safety profile in as little as three days, compared to the weeks or months required of classical toxicology methods.

## 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 21 IVD companies.

| Up | Price | % Chg |
|---|---|---|
| Abbott Labs | $47.64 | 4% |
| Affymetrix | 25.82 | 24 |
| Beckman Coulter | 60.94 | 6 |
| Bio-Rad | 74.88 | 6 |
| Cholestech | 16.09 | 29 |
| Cytyc | 26.76 | 14 |
| Digene | 47.22 | 6 |
| Gen-Probe | 48.54 | 2 |
| Immucor | 27.14 | 11 |
| Inverness Medical | 37.40 | 5 |
| Johnson & Johnson | 67.81 | 4 |
| OraSure | 8.21 | 2 |
| Quidel | 15.39 | 5 |
| Third Wave | 4.42 | 2 |
| **Unchanged** | | |
| Bayer | 50.49 | 0 |
| **Down** | | |
| Abaxis | 19.90 | -12 |
| Becton Dickinson | 70.52 | -2 |
| Biosite | 45.81 | -7 |
| Dade | 36.72 | -8 |
| Meridian | 22.09 | -6 |
| Ventana | 39.37 | -5 |

# G-2 Insider

**Roche Launches Hepatitis C Campaign . . .** Over the past year, Digene has urged consumers to "tell someone" about human papilloma virus (HPV) testing through a media blitz that includes PSA-style TV ads and a print campaign that has inserted pastel-colored "tell someone" postcards in virtually every women's magazine on the newsstand. Now the North American division of Roche (Basel, Switzerland) is launching a similar strategy with another disease: hepatitis C (HCV).

*HCV is a viral infection of the liver that affects an estimated four million Americans, 70% of whom are unaware of their disease.*

HCV is the most common blood-borne viral infection in the United States, and CDC estimates the number of HCV-related deaths could increase to 38,000 annually by 2010, surpassing annual HIV/AIDS deaths. Initial diagnosis of hepatitis C is usually determined with a blood test, but routine blood tests and yearly physicals typically do not include screening for HCV.

Roche's new campaign, Hep C STAT! (Stop, Test, And Treat), encourages individuals to consider their risk factors for HCV, get tested, and, if infected, talk with a liver specialist about treatment options. The face of the campaign is author and actor Christopher Kennedy Lawford, who was diagnosed and successfully treated for HCV.

In addition to the HCV immunoassays first cleared by the FDA in 1990, RNA-based tests can qualitatively detect the presence or absence of the HCV virus and quantify viral titers. Genotyping is also useful in HCV, as there are six known genotypes and more than 50 subtypes of the virus. Knowing a patient's HCV genotype or serotype can assist clinicians in making treatment decisions, as patients with certain genotypes are more likely to respond to certain therapies, such as alpha interferon and ribavarin, which Roche manufactures under the trade names Pegasys and Copegus.

## Company References

Access Genetics 952-942-0671
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ARUP 801-583-2787
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Health Systems Concepts 407-774-5291
Iconix 650-567-5500
Innogenetics 32-9-329-13-29
Mayo Clinic 507-284-2511
Orion Genomics 314-615-6977
Panacea Laboratories 240-404-9045
Qiagen 800-362-7737
Roche Diagnostics 41-61-688-1111
Saladax Biomedical 610-419-6731
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