Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

FDA Approves First RNA Test For HIV Diagnosis

The FDA has approved the Aptima HIV-1 RNA test, a qualitative molecular assay that detects the RNA of the HIV-1 virus. Manufactured by Gen-Probe (San Diego, CA), Aptima is the first test approved for the detection of HIV-1 RNA to help diagnose HIV-1 infection, and it can detect primary HIV-1 infection earlier than HIV antibody tests. The assay was previously only available as part of a larger kit used to screen blood and plasma donors, explained Jay Epstein, M.D., director of the Office of Blood Research and Review at the FDA's Center for Biologics Evaluation and Research.

The test could be an alternative to the traditional Western blot test that is used to confirm HIV-1 infection after positive antibody screening. Western blots can be difficult to interpret and inconclusive. The Aptima test is also a promising method for early detection of HIV-1 infection, as it can detect the infection even before HIV-1 antibodies have appeared. The assay's sensitivity is comparable to that of FDA-approved viral load assays, but unlike viral load tests, it has been approved for the diagnosis of primary HIV-1 infection, as well as for confirming HIV-1 infection when tests for antibodies to HIV-1 are positive.

Despite its diagnostic utility, HIV RNA level has recently been shown to be a poor predictor of the rate of CD4 cell loss in HIV patients and therefore of questionable usefulness in treatment decisions. For more information on this recent study, see page 8.

CMS Plans New Guidance For Genetic Testing Specialty Inspections

CMS, CDC, and FDA, the various branches of the Department of Health & Human Services (HHS) that share jurisdiction over Clinical Laboratory Improvement Amendments (CLIA), have officially decided to take "Draft CLIA specialty requirements for genetic testing" off of their to do list, putting to rest years of speculation and anticipation about the rulemaking effort and when a draft rule would be released. Federal officials informed the Clinical Laboratory Improvement Advisory Committee of the decision to not proceed with the rule-making effort at its recent meeting in Atlanta.

In lieu of formulating new CLIA rules concerning genetic testing, CMS intends to strengthen oversight of genetic testing labs under extant CLIA regulations. This includes new guidance for inspections, inspector training, and educational guidance for labs that perform genetic testing. CMS also plans to work with the CDC and FDA on complex analytical test validations and continuing oversight of genetic testing labs.

OncoPlan Shown To Identify Best Chemo Candidates

A study presented at the American Association for Cancer Research's Molecular Diagnostics in Cancer Therapeutic Development Conference found that OncoPlan, the commercially available cancer test developed and marketed by Catalyst Oncology (Worcester, MA) can help to distinguish breast cancer patients that will benefit from chemotherapy from those who won't.

Introduced in August of 2005, OncoPlan is an immunohistochemical test that measures two forms of the Shc protein: tyrosine-phosphorylated (PY)-Shc, which appears to act as an oncogene, and p66 Shc, which acts as a tumor suppressor. Previous studies have shown that OncoPlan can predict the aggressiveness of a tumor as well as the relative risk of disease recurrence following surgery in breast, colon, and gastric cancers.

Founded by Steve DiPalma, its current CEO and president, Catalyst offers OncoPlan for clinical testing of patients with all three cancers through its CLIA-certified laboratory. The company also offers testing for HER2/neu, estrogen and progesterone receptors, and Ki-67 for breast cancer.

Given that chemotherapy-mediated killing of tumor cells does not require p66 Shc, the researchers set out to investigate whether those patients whose tumor cells have low levels of p66 Shc would respond well to chemotherapy. They examined Shc proteins in tumors from 2,380 women diagnosed with invasive breast cancer, 717 of whom had received chemotherapy.

Those patients who had low levels of p66 Shc and did not receive chemotherapy had very poor outcomes, but similar patients who received chemotherapy reduced by at least two-fold their chances of relapsing and dying from breast cancer. Those women with high levels of p66 Shc were much more likely to survive the disease but seemed to derive no benefit from chemotherapy.

According to the study's lead investigator, ongoing studies will address possible associations between PY-Shc and chemotherapy. Further validation in clinical trials will be necessary to use OncoPlan to direct treatment decisions. The test is currently used to predict disease aggressiveness.

Endometrial and Uterine Cancer Screening Test To Enter Clinical Trials

CytoCore (Chicago, IL) will soon begin Phase I clinical trials of its endometrial and uterine cancer screening test, which combines microscopy with a genetic marker that identifies pre-cancerous cell changes.

With an estimated wholesale price of $100, CytoCore's InPath System uterine and endometrial cancer scan could provide a valuable method of early detection. The rapid, minimally invasive test consists of an "endometrial collector" that gathers endometrial cells from the uterus. The collected cells are then tested for the expression of two biomarkers, which are visualized using a computer-guided image recognition microscope system.

CytoCore plans to complete Phase I trials for its endometrial cancer scan within the next six months. Completion of Phase II trials and FDA approval are estimated by the company to be two years away.

NCI Creates Clinical Proteomics Network For Cancer Diagnostics

"This is the future of cancer detection in America," said Fred Regnier, Ph.D.

In the latest phase of its $104 million Clinical Proteomic Technologies Initiative for Cancer (CPTI), the National Cancer Institute (NCI; Bethesda, MD) has established a network of proteomic research teams to assess measurement technologies for proteins and peptides relevant to clinical cancer research and practice. The NCI awarded $35.5 million over five years to unite five teams from around the United States in the Clinical Proteomic Technology for Cancer (CPTAC) program.

Proteomics, the study of the structure and function of proteins, has long been heralded as the "next big thing" in biomedicine, and the CPTI was developed to address the scientific requirements for realizing the promise of proteomics in clinical oncology. "This is the future of cancer detection in America," said Fred Regnier, Ph.D., a professor at Purdue University and lead investigator of the CPTAC team there.

CPTAC Teams

Broad Institute of MIT and Harvard (Cambridge, MA)

University of California, San Francisco and Lawrence Berkeley National Laboratory

Vanderbilt University School of Medicine (Nashville, TN)

Purdue University (West Lafayette, IN)

Memorial Sloan-Kettering Cancer Center (New York, NY)

While proteomics has been advanced by such achievements as the mapping of the human genome, more precise mass spectrometry, and the development of protein microarrays, significant challenges remain. The vast proteome is highly complex, and since cells continually modify proteins once they are produced, the types of proteins measured can vary from person to person. Proteins also exist in a variety of concentrations in the body, and unlike DNA, there is no way to make copies of proteins that exist in very small amounts.

"Emerging proteomic technologies have potential to improve cancer diagnostics and treatment," said NCI Director John E. Niederhuber, M.D. "But we must carefully, consistently, and systematically examine them at every major step in the measurement process, in order to realize their full potential." A primary objective of CPTAC will be the standardization of proteomic technologies and methodologies, which will expedite the discovery of biomarkers that will in turn improve cancer diagnostics, therapeutics, and preventative measures.

Specific objectives of CPTAC program teams:

- ❑ To evaluate the performance of proteomic technology platforms and to standardize approaches to developing applications of these platforms;
- ❑ To assess proteomic platforms for their ability to analyze cancer-relevant proteomic changes in human clinical specimens;
- ❑ To establish systematic ways to standardize proteomic protocols and data analysis among different laboratories;
- ❑ To develop and implement uniform algorithms for sharing bioinformatics and proteomic data and analytical data/mining tools; and
- ❑ To develop well-characterized material and bioinformatics resources for the entire cancer research community.

Source: NCI

The teams selected come from a variety of disciplines and have experience with a wide range of proteomic technologies. The Purdue team, for example, pairs experts in mass spectrom-

etry and proteomics technology with clinical cancer researchers from Indiana University School of Medicine. Together, they will develop protocols and standards for mass spectrometry-based cancer proteomics relating to breast and prostate cancer. "Remarkably, all five centers included breast cancer as an area of study, which will allow for incredible scientific collaboration and evaluation of data from patients nationwide," added Regnier.

Roche And OraSure To Collaborate On Saliva-Based Drug Tests

Roche Diagnostics (Basel, Switzerland) and OraSure Technologies (Bethlehem, PA) have agreed to co-develop and commercialize fully automated oral fluid drugs of abuse assays that can run on random access chemistry analyzers, allowing them to be processed with the same efficiency as urine-based tests and potentially decreasing turnaround time.

The tests will use OraSure's Intercept oral specimen collection device and Roche's KIMS kinetic interaction of microparticles in solution (KIMS) technology. Intercept is the only FDA-cleared in vitro diagnostic laboratory-based oral fluid testing system for drugs of abuse detection.

OraSure Chief Science Officer Stephen R. Lee, Ph.D., predicts that that ability of labs to run the new assays enable on advanced, flexible chemistry analyzers "should ultimately lead to higher volumes of oral fluid testing." The increased ease of sample collection could also make drugs of abuse more appealing to many organizations.

Foundation Offers $10M For Cheap Gene Test

Having conquered space, the X Prize Foundation (Santa Monica, CA) has set its sights on the real final frontier: the human genome. The private nonprofit organization, best known for awarding $10 million for the first private space flight, recently announced its second such competition. Designed "to revolutionize the medical world," the $10 million Archon X Prize for Genomics will be awarded to the first team that can build a device and use it to sequence 100 human genomes within 10 days or less, with an accuracy of no more than one error in every 10,000 bases sequenced, with sequences accurately covering at least 98% of the genome, and at a recurring cost of no more than $10,000 per genome.

In 2000, J. Craig Venter, Ph.D., led the first private team to successfully sequence a complete human genome. Nine months and $100 million later, that team accomplished the task. In September 2003, Venter's own foundation offered a $500,000 prize designed to encourage development of less expensive and faster sequencing technology. This prize has since been folded into the Archon X Prize.

At press time, three teams had already signed up to compete for the prize: VisiGen Biotechnologies (Houston, TX) led by Susan Hardin Ph.D., 454 Life Sciences (Branford, CT) led by Christopher McLeod, and a third team, which is a Gainesville, Florida-based consortium of researchers from the Westheimer Institute for Science and Technology, the Foundation for Applied Molecular Evolution, and Firebird Biomolecular Sciences.

Esoteric Testing Keeps Growing, Labs Look To Bring More Tests In-House

Although the number of top esoteric testing * laboratory facilities has recently shrunk from 22 to 14 due to industry consolidation, growth in this area has been very strong. In 2003, the 22 top esoteric labs had a combined total annual revenue of $3.66 billion. In 2005, the remaining combined 14 top esoteric lab service providers had a total combined annual revenue of $12.24 billion, representing 335% growth in revenues over a two-year period. The market is dominated by Quest (with 45% of the market), Genzyme (22%), LabCorp (22%), and AmeriPath (5%).

Top 4 Esoteric Laboratory Testing Providers by Estimated Annual Revenue, 2005

Laboratory	*2005 Revenue ($MM)*
Quest	$5,504
Genzyme Genetics	2,700
LabCorp	2,697
AmeriPath	563.6

Source: *DTTR* and company reports

The below table lists the most common tests sent out by hospitals and independent labs to esoteric testing laboratories. The price data listed is the average prices paid by the referring labs for each test after all discounts. The unweighted average price is $36.68.

Pricing for 25 Most Frequently Referred Tests

Test Name	*Average Price*
Antinuclear antibody test (ANA)	$9.81
Chlamydia/GC DNA probe	22.20
Lead (blood)	8.02
Vitamin B12	7.91
Parathyroid hormone	21.59
Hepatitis ABC panel	48.21
HIV antibody	9.05
Homocysteine	24.30
CA 27-29	18.41
Folate	20.60
Hemoglobin A1c	9.72
Human papillomavirus (HPV-high risk)	65.63
Hepatitis C antibody	13.35
Microalbumin	10.97
Vitamin D	30.44
AFP triple test	28.33
Cystic fibrosis genetic analysis	168.73
CA-125	17.08
Hepatitis C viral load	125.61
Lyme disease	33.88
Testosterone (free and total)	40.22
Free T3	18.12
C-reactive protein	17.15
HIV viral load	128.20
Zinc	19.44
Unweighted Avg. Price	36.68

Source: *U.S. Laboratory Reference Testing: Market Profile & Pricing Trends 2005*, Washington G-2 Reports

A 2004 Washington G-2 Reports survey found that the primary reason laboratories didn't bring esoteric tests in-house was the low-test volumes didn't justify it. This was down slightly (39%) in 2004 compared to a similar survey in 2002 (46%). This 7% shift could be a statistical anomaly, a reflection on how demand for some esoteric tests are bringing volumes up, or indicative of how automation for some esoteric tests has made them cost-effective at relatively low volumes. The second most commonly cited reason (16%) was "budget constraints/lack of capital to purchase necessary equipment," which has remained the same over that two-year period. Generally speaking, there were no great changes in any of the survey results except that "not enough space" went from 3% in 2002 to 9% in 2004 and "inadequate reimbursement from Medicare and/or managed care payers" dropped from 16% to 11%.

What Is the Biggest Barrier Your Laboratory Faces in Expanding its Esoteric Testing Menu?

	2002	2004
Low test volumes do not justify bringing in-house	46%	39%
Budget constraints/lack of capital to purchase necessary equipment	16%	16%
Inadequate reimbursement from Medicare and/or managed care payers	16%	11%
Esoteric testing reagents are too expensive	10%	11%
Difficulty in hiring laboratory staff with necessary expertise	9%	9%
Not enough space	3%	9%
Other reason	0%	5%

Source: *U.S. Laboratory Reference Testing: Market Profile & Pricing Trends, 2005*

Which Tests Are Labs Bringing In-House?

Surveys performed by Washington G-2 Reports indicate that many labs are increasing their efforts to bring more esoteric reference tests in-house. The tests most frequently cited by higher-volume labs that they expect to bring in-house are cystic fibrosis genetic analysis, hepatitis C viral load, and HIV viral load. Lower-volume labs indicate they plan to add tests for folate, CA 125, and vitamin B12.

Tests Expected to Be Brought In-House (2005)

*Higher-volume Labs**	*Lower-Volume Labs***
1) Cystic fibrosis (genetic analysis)	1) Folate
2) Hepatitis C viral load	2) CA 125
3) HIV viral load	3) Vitamin B12
4) Cytomegalovirus (CMV) viral load	4) B-type natriuretic peptide (BNP)
5) Human Papillomavirus (HPV)	5) HIV antibody
6) High-sensitivity CRP	6) Free T3
7) Hepatitis C antibody	7) Hepatitis B surface antigen

* Labs performing more than one million billable tests per year

** Labs performing one million or less billable tests per year

Source: Washington G-2 Reports' Second National Esoteric Testing Survey

* *DTTR* defines esoteric testing as tests that are too high in complexity and too low in volume to be regularly performed within a hospital or routine independent lab, plus similarly complex tests sent out by physician office laboratories.

New Microscopic Observation Test For TB Is Faster, Cheaper

Every year, 1.7 million people die of tuberculosis, according to the World Health Organization.

A newly developed test for tuberculosis (TB) promises a faster, cheaper, and more sensitive alternative to current culture-based tests for the curable disease. A study on the test, known as microscopic-observation drug-susceptibility (MODS), appears in the October 12 issue of the *New England Journal of Medicine*.

The MODS assay, in which broth cultures are examined microscopically to detect growth characteristic of TB, has been previously shown to distinguish patients with TB from healthy controls. In the *NEJM* study, researchers explored how effectively the test distinguished between patients with and those without active tuberculosis among those with suspected tuberculosis. Additionally, the study examined if the test could distinguish drug-resistant disease from drug-sensitive disease.

Led by David A.J. Moore, M.D., of Imperial College London, the researchers tested 3,760 sputum samples using MODS and the two current gold standard TB tests: the Lowenstein-Jensen culture and automated mycobacterial culture. To test the samples using MODS, the cultures were observed under an inverted light microscope for 40 days. The sensitivity of detecting TB was 97.8% for MODS culture, 89% for automated mycobacterial culture, and 84% for Lowenstein-Jensen culture. The median time for detection of TB was seven days for MODS culture compared to 13 and 26 days for automated mycobacterial culture and Lowenstein-Jensen culture, respectively.

To detect drug-resistant TB, the researchers introduced five TB antibiotics to the cultures. Compared to standard culture reference methods, drug-resistant susceptibility agreement for MODS ranged from 100% (for rifampin) to 92% (for streptomycin). MODS results were available in an average of seven days, whereas standard antimicrobial tests can take up to several months.

"The MODS assay addresses two key gaps in resource-limited settings with a high tuberculosis burden: rapid, accurate detection of *M. tuberculosis* and simultaneous identification of multi-drug-resistant tuberculosis," wrote the authors. "Our study defines strengths and redundancies in the first-generation MODS assay and should enable the development of a streamlined, clinically useful method." MODS testing requires a trained technician to perform the test. The authors noted that the 10-day technician training period is comparable to that for reading malaria smears.

The microscopic-observation drug-susceptibility (MODS) assay for the detection of tuberculosis and multi-drug-resistant tuberculosis, directly from sputum, relies on three principles:

- Mycobacterium tuberculosis grows faster in liquid medium than in solid medium
- Characteristic cord formation can be visualized microscopically in liquid medium at an early stage
- The incorporation of drugs permits rapid and direct drug-susceptibility testing concomitantly with the detection of bacterial growth

In an editorial in the same issue of *NEJM*, Michael D. Iseman, M.D., and Leonid B. Heifets, M.D., noted the major obstacle to implementing this cultivation method in the developing regions where it is most desperately needed: biosafety. "Implementation of an 'inexpensive' test can be successful only if it is incorporated into the overall algorithm of the laboratory protocol," wrote Iseman and Heifets. "The establishment of microbiology laboratories in countries with a high prevalence of tuberculosis and growing rates of drug-resistant tuberculosis should become one of the urgent priorities in the global fight against tuberculosis epidemics. The MODS technique may well move this process forward."

JAMA Study Finds HIV RNA Level Of Little Value In Treatment Decisions

"These findings represent a major departure from the notion that plasma HIV RNA level is a reliable predictor of rate of CD4 cell loss in HIV infection…."

Blood levels of HIV are poor predictors of the rate of CD4 cell loss in untreated HIV-infected individuals, according to a study published in the September 27 issue of the *Journal of the American Medical Association*.

Plasma HIV RNA level is thought to be similar to CD4 cell count in its ability to both predict the short-term risk of HIV progressing to AIDS and to serve as a marker for the effectiveness of antiretroviral therapy, but it was previously unknown to what degree HIV RNA level could predict the rate of CD4 cell loss. This study, led by Benigno Rodríguez, M.D., of Case Western Reserve University, sought to examine how these measures are related.

After conducting a repeated analysis of 2,801 untreated HIV patients, the researchers found that although higher baseline (or "presenting") HIV RNA levels were associated with greater subsequent CD4 cell decline, only 4% to 6% of CD4 cell loss variability could be explained by plasma HIV RNA level. The results suggest that in chronic, untreated HIV infection, over 90% of the factors that determine CD4 cell loss are not reflected in the amount of virus in blood at the time of initial medical evaluation.

"These findings represent a major departure from the notion that plasma HIV RNA level is a reliable predictor of rate of CD4 cell loss in HIV infection and challenge the concept that the magnitude of viral replication (at least as reflected by plasma levels) is the main determinant of the speed of CD4 cell loss at the individual level," wrote the authors. They concluded that in most cases, because an individual's presenting HIV RNA level cannot predict the rate of CD4 decline, the measurement is of limited clinical value in shaping the decision to initiate antiretroviral therapy.

In an accompanying editorial, W. Keith Henry, M.D., and others discussed the study's findings and highlighted its clinical implications, concluding that: "The seemingly useful practice of combining a CD4 cell count and plasma HIV RNA levels to assess an individual patient's prognosis for AIDS progression or response to highly active antiretroviral therapy needs re-examination."

On a more optimistic note, Henry et al. noted that the study's findings also imply that an improved understanding of the various and as yet poorly understood factors that drive HIV-associated CD4 cell loss could translate to novel therapeutic and diagnostic approaches.

HIV Testing Up 50% In NYC, State Struggles With New CDC Guidelines

What a difference a year makes. That's how long it took for HIV testing to increase by almost 50% in New York City, according to newly released statistics from clinics, hospitals, and jails owned by the city. Meanwhile, New York state is struggling with a state law that makes it impossible to adopt the recently released Centers for Disease Control and Prevention (CDC) guidelines recommending routine HIV testing for all adults and adolescents.

In the 11 hospitals and five family clinics owned by the Health and Hospitals Corporation (HHC; New York City), 63% more people were tested for HIV in 2006, and

About one in four HIV diagnoses comes when the patient is found already to have developed AIDS.

of the 92,000 tested, 1,514 patients were found to have HIV, up from 720 in 2005. Over the next year, HHC plans to test 150,000 patients.

Not only are more people getting tested for HIV, but the profile of that population is changing. Once dominated by pregnant women, for whom HIV testing is nearly universal, the population receiving tests today is increasingly diverse. At HHC facilities, 90% of those tested were minorities and 82% were women.

What's Driving the Growth in NYC?

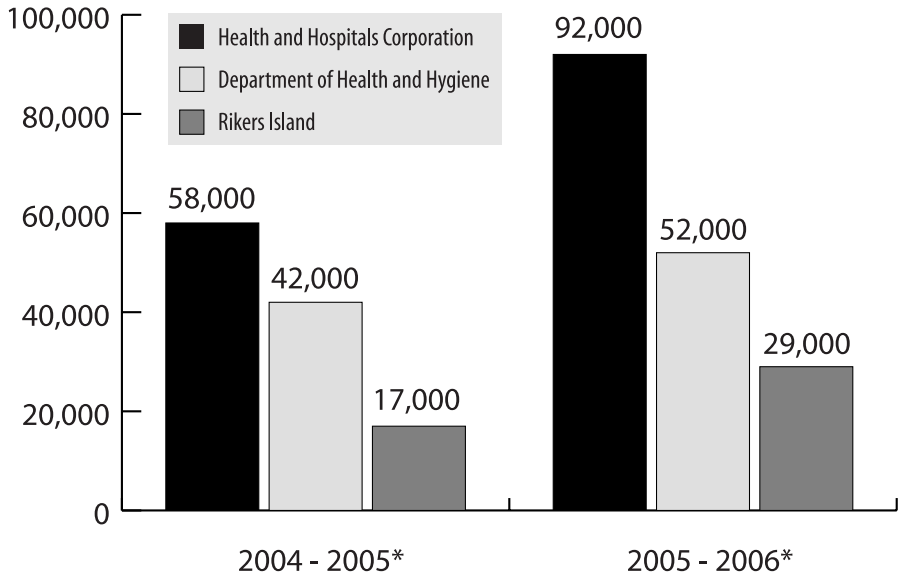
A number of factors are driving the recent growth spurt in HIV testing in New York City, including the efforts of Mayor Michael Bloomberg's administration, which has long urged routine HIV screening for city residents. HHC has been aggressive in its efforts to offer testing to patients that come in for physicals or unrelated conditions.

Another key contributor to the growth in testing is the introduction of simple, rapid HIV tests, which can be performed at the point of care and visually read within 20 minutes, including oral fluid-based tests such as OraQuick's Advance HIV 1/2 antibody test, which was recently cleared by the FDA. Also contributing to the uptick in testing is the New York Department of Health's 2005 decision to reduce the amount of pretest counseling that it requires patients to receive.

New York State Law and HIV Testing

Despite the progress in New York City, the state of New York faces a controversial legal obstacle to implementing the recently released CDC guidelines for HIV testing, which recommend making testing a routine part of doctor's visits. New York has the highest rates of HIV infection in the country. It also still has on its books a law passed in the 1980's that requires that patients sign an "informed consent" form, which explains the test and the patient's rights and is different from standard test consent forms, before an HIV test can be ordered.

HIV Testing in New York City



*From July 1, 2004, to June 30, 2005
**From July 1, 2005, to June 30, 2006

The law, originally intended to protect the rights of those with HIV and AIDS, mandates that the HIV test consent form include, among other information, cautionary language concerning possible discrimination problems relating to the disclosure of the test results. The state of New York also requires pre- and post-test counseling.

New York City Health Commissioner Thomas Frieden, a vocal opponent of the law, is working to eliminate the need for patient consent to HIV testing, but many advocacy groups are opposed to weakening the protections in place. The CDC guidelines advise providers to inform patients that they will be tested for HIV but do not request their permission nor provide pre- or post-test counseling.

Most Patients Uninformed About Triglycerides, Study Finds

According to the American Heart Association, 100 million Americans are living with unhealthy lipid levels.

Patients are unaware of the cardiovascular risks associated with unhealthy levels of triglycerides, according to a recent study commissioned by the National Lipid Association (NLA). The survey of 2,089 patients and 510 doctors found that patients do not understand triglycerides and are unaware of both the risks they may pose to heart health and how they differ from cholesterol.

Triglycerides, which are a type of fat produced by the body and ingested from food, are measured as part of standard lipid blood tests. Elevated triglycerides are linked to such illnesses as heart disease, kidney disease, and pancreatitis.

Education of and by physicians is an important part of solving the problem of uninformed patients, says Jerome D. Cohen, M.D., director of Preventive Cardiology Programs at St. Louis University Health Sciences Center and chairman of the NLA Consumer Affairs Committee "A first step is for doctors to make sure they understand current guidelines, as those surveyed felt they were less familiar with triglyceride guidelines than with those for 'good' or 'bad' cholesterol."

G-2 Award Winners Honored At Lab Institute 2006

Michael Laposata, M.D., Ph.D.

Michael Laposata, M.D., Ph.D., is the recipient of Washington G-2 Reports's 2006 Laboratory Public Service National Leadership Award, an annual honor that recognizes an individual who has made a significant contribution to the public interest through accomplishments that directly enhance patient care and the lab profession. **Arikpo Ondo**, a student at Rush University Medical Center in Chicago, was awarded the Dennis Weissman/Washington G-2 Reports' Scholarship for Excellence in Clinical Laboratory Sciences. Laposata and Ondo received their awards in a special presentation on September 28 at Lab Institute 2006 in Arlington, VA.

A board-certified clinical pathologist, Laposata serves as director and chief of the division of clinical laboratories at the Massachusetts General Hospital and a professor of pathology at Harvard Medical School. "Mike has substantially upgraded the role of laboratory medicine in patient care," wrote one colleague in his nomination of Laposata. "He has championed the importance of outreach to our clinical colleagues, particularly through his results interpretations."

Arikpo Onda

Onda was selected for demonstrated leadership potential and excellence in the clinical laboratory sciences curriculum. At Rush University, she serves as vice president of the CLS student club, and she recently began her tenure as the student forum chairperson for the Illinois chapter of the American Society for Clinical Laboratory Science.

IVD Stocks Up 13% Year To Date Led By Digene and Inverness

Twenty-one IVD companies have risen an unweighted average of 13% through October 6, 2006, with 13 stocks up in price and eight down. This compares with the 8% rise in the S&P 500 and the Nasdaq, which is up 4% for the year.

Interestingly, the best *and* worst performing stocks are molecular diagnostics companies. **Digene** (Gaithersburg, MD), which is responsible for making HPV a household name thanks to its "Tell Someone" media blitz, has soared an amazing 53% this year to $44.51 per share for a market capitalization of $1.10 billion. California recently became the fifth state in the nation to require insurers to cover HPV testing as part of cervical cancer screening.

Also performing strongly is **Inverness Medical Innovations** (IMA; Waltham, MA), which is up 51% to $35.74 per share for a market cap of $1.23 billion. The company recently acquired worldwide exclusive marketing rights to Chembio's FDA-cleared, point-of-care HIV test and exclusive U.S. marketing rights to Chembio's proprietary lateral flow cassette test for HIV antibodies.

The worst performing stock has been the ever-volatile GeneChip maker **Affymetrix** (Santa Clara, CA), down 56% to $20.83 per share for a market cap of $1.47 billion. One Wall Street analyst described the investment community as "flummoxed by the continued spate of revenue and earnings disappointments."

IVD Stock Performance, YTD Through October 6, 2006

Company (ticker)	12/31/05 Price	10/7/05 Price	YTD %Chg	P/E Ratio
Digene (DIGE)	29.17	44.51	53	122
Inverness Medical (IMA)	23.71	35.74	51	N/A
Third Wave (TWTI)	2.98	4.35	46	N/A
Immucor (BLUD)	17.61	24.50	39	42
Abaxis (ABAX)	16.48	22.61	37	53
Quidel (QDEL)	10.76	14.69	37	42
Cholestech (CTEC)	9.92	12.46	26	35
Becton Dickinson (BDX)	56.90	71.82	26	26
Bayer (BAY)	41.76	50.56	21	22
Meridian (VIRO)	20.14	23.56	17	35
Abbott Labs (ABT)	39.43	45.90	16	23
Bio-Rad (BIO)	65.44	70.75	8	21
Johnson & Johnson (JNJ)	60.10	65.06	8	17.5
Ventana (VMSI)	42.35	41.54	-2	58
Dade (DADE)	40.89	39.82	-3	24
Gen-Probe (GPRO)	48.79	47.38	-3	41
Beckman Coulter (BEC)	60.08	57.32	-5	28
OraSure (OSUR)	8.82	8.08	-8	13.5
Biosite (BSTE)	56.29	49.22	-13	19
Cytyc (CYTC)	28.23	23.53	-17	24
Affymetrix (AFFX)	47.75	20.83	-56	46
Unweighted Avg.			13%	

G-2 Insider

Sweet Charity In The Diabetes Market . . . Becton, Dickinson & Company (BD; Franklin Lakes, NJ) will exit the blood glucose monitoring market by the end of next year due to intense competition for market share. *DTTR* estimates BD's glucose business at about $95 million in sales.

In the wake of BD's announcement, Abbott Laboratories (Abbott Park, IL), Roche Diagnostics (Basel, Switzerland), and Johnson & Johnson subsidiary Lifescan (Milpitas, CA) are wooing BD customers. All three companies have offered free blood glucose meters and test strips to customers who use BD's soon-to-be-discontinued products.

According to the National Institutes of Health, about 20.8 million people in the United States have diabetes, the most common cause of blindness, kidney failure, and amputations in adults.

Is a genetic test for Type 2 diabetes in the future? Those with two copies of a single nucleotide polymorphism (SNP) found in the TCF7L2 gene on chromosome 10q25.3 are 1.4 times more likely to develop Type 2 diabetes, while those with two copies have twice the risk. The hallmarks of Type 2 diabetes, which accounts for up to 95% of all diabetes cases, are insulin resistance and a gradual failure of beta cells to produce enough insulin. This gene variant is associated with decreased insulin production, but not with any increase in insulin resistance.

deCode Genetics (Reykjavik, Iceland), which discovered the gene variant, plans to market a test based upon it within the next few years, although diabetes researchers and advocacy groups have questioned the usefulness of such a test at this early stage. deCode's CEO has speculated that the test would initially be used with patients who have impaired glucose tolerance.

Company References

Abbott Laboratories
847-937-6100
Becton, Dickinson & Co.
201-847-6800
Catalyst Oncology
508-770-1980
CytoCore 312-222-9550
deCode Genetics
354-570-1900
Gen-Probe 800-523-5001
Lifescan 800-227-8862
National Cancer Institute
800-422-6237
OraSure 800-869-3538
Roche Diagnostics
41-61-688-1111
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