Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Stephanie Murg, Managing Editor, smurg@ioma.com

Vol. VII, No. 2/October 2006

CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

Quidel Launches FDA 510(k)-Cleared RSV Test

Point-of-care diagnostic test maker Quidel (San Diego, CA) has received FDA 510(k) clearance for its QuickVue test for respiratory syncytial virus (RSV), which causes about 100,000 hospitalizations per year in the United States and is the leading cause of bronchiolitis and pneumonia in children under two years old. The test allows for the rapid, qualitative detection of RSV from nasopharyngeal swab and nasopharyngeal aspirate specimens from symptomatic patients 18 years of age and younger.

RSV testing is usually only ordered during the RSV season, which runs from late fall to early spring, on patients who have moderate to severe symptoms and lower respiratory tract involvement. It is primarily ordered on infants, elderly patients, and those with compromised immune systems. Reimbursement for the test is under CPT code 87420, for which the national limit is set at $16.76, according to the 2006 clinical laboratory fee schedule. Quidel has set a list price of $227.50 for a box of 20 QuickVue RSV tests, a company representative tells *DTTR*.

Quidel's test will compete directly with Binax's NOW RSV test, a rapid immunochromatographic assay that is both CLIA waived and FDA approved, and Inverness Medical's Clearview RSV test. Other RSV tests include BD's Directigen RSV Test, Fisher's Sure-Vue RSV Test Kit, and the ImmunoCard STAT! RSV test manufactured by Meridian Bioscience.

Cytyc Trumps Ventana In Bidding War For Vision Systems

It's not over 'til it's over when it comes to multi-million dollar acquisitions, and the deal for anatomical pathology automation company Vision Systems (Melbourne, Australia) is no exception. Ventana Medical Systems (Tucson, AZ) had offered $356 million for nine-year-old Vision, and management speculated optimistically on the long-term growth synergies of the combined company (see *DTTR*, September 2006, pg 1-2). But just as Ventana shareholders were getting excited, Pap smear giant Cytyc (Marlborough, MA) swooped in with a bid of $374 million on September 14, boosting shares in Vision by 11%.

Cytyc has no product overlap with Vision, which has a market share of about 10% to 15% in the United States. Ventana, which has about 70% of the U.S. anatomical pathology market, is not taking the news lightly. While they have pledged not to up their bid, they have announced their intent to immediately file patent litigation against Vision in U.S. federal court. According to Ventana, the company had deferred filing the intellectual property suit pending the outcome of the planned acquisition.

Breast Biopsy Device Maker Rubicor Medical Gets $30 Million

Privately held Rubicor Medical (Redwood, CA), an eight-year-old developer and distributor of breast biopsy devices, has secured $30 million in private equity funding from a consortium led by Safeguard Scientifics (Wayne, PA). The buyout firm, which also owns 57% of cancer diagnostics company Clarient, provided $20 million of the Series C financing, with the balance from ITX International Equity Corporation and Rubicor's founding shareholders. Safeguard now holds a 34% stake in Rubicor.

Founded by cardiologist James W. Vetter, M.D., Rubicor has developed three products as alternatives to existing breast biopsy devices. The minimally invasive devices, all of them FDA cleared, result in a more accurate assessment of the tumor sample and include evaluation of margin and determination of size. The lead product, Ovation, enables retrieval of a complete, contiguous tissue sample, making it an attractive alternative to open surgical biopsy. The other devices are Bravo, which is a self-contained rotational core biopsy device, and GentleWrap, a compression wrap for use after procedures such as biopsy or lumpectomy. The breast cancer diagnostics market in which Rubicor competes is estimated at more than $500 million in the United States.

Iris Diagnostics Gets LabCorp Contract For Urinalysis

LabCorp (Burlington, NC) has awarded a five-year contract for urinalysis to the diagnostics division of Iris International (Chatsworth, CA). Under the terms of the agreement, Iris will supply and service automated urine microscopy technology for LabCorp, as well as provide training, installation, service, and related reagents and consumables. Financial terms of the agreement were not disclosed.

As part of the agreement, LabCorp has ordered 26 of Iris's iQ 200 Sprint urine microscopy analyzers, which are fully automated bench-top systems that perform complete urinalysis on unspun specimens. The iQ 200 Sprint platform has a throughput of 101 tests per hour and features software that classifies urine particles into 12 categories and quantitatively reports results. According to Cesar Garcia, president and CEO of Iris, the company has installed iQ 200s in five of the top six hospitals in the United States.

In the company's second quarter conference call, Garcia was enthusiastic about Iris's multi-unit, multi-side deals. "That is really good for continued penetration but you're now looking into much higher capital appropriations," he said. "And you have much more financial scrutiny by the CEOs and the CFOs of the hospitals."

In addition to automated urinalysis systems, Iris develops molecular diagnostics and manufactures blood analysis products. The company's sales for the first half of this year totaled $32.8 million, up 11% compared to the first half of 2005. While continuing to focus on increasing domestic sales and expanding distribution, Iris will introduce urinalysis products geared toward low-volume users.

Innogenetics Triumphs Over Abbott In HCV Patent Case

Belgian biotech company Innogenetics (Gent, Belgium) has won its patent case against Abbott Laboratories (Abbott Park, IL) in U.S. District Court. On Sep-

tember 8, a Wisconsin jury unanimously found that Abbott willfully infringed Innogenetics' patent covering a method for genotyping the hepatitis C virus (HCV). The verdict directs Abbott to pay Innogenetics $7 million, an award that may be increased subject to the judge's discretion.

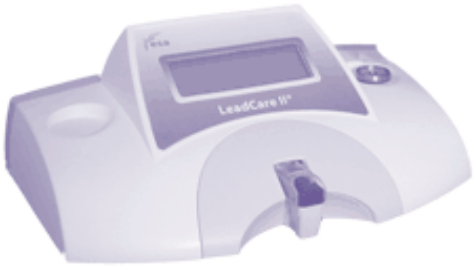
In February of this year, Innogenetics resolved a similar dispute with Third Wave Technologies (Madison, WI). As part of the resolution of the litigation, Immunogenetics granted Third Wave a nonexclusive license to sell HCV genotyping products in the United States. The agreement also includes certain opt-out rights for Third Wave, as well as an option to extend both the term and global reach of the license. Financial terms of the deal were not disclosed.

Founded in 1985, Innogenetics earned 2005 revenues of €48.6 million (about $62 million). Earlier this year, the company said that its 2006 revenue forecast of €68 million ($87.1 million) relied on receiving a significant amount of royalties from Abbott. Innogenetics' profitable specialty diagnostics division focuses on infectious diseases, genetic testing, and neurodegeneration. The company also develops therapeutic vaccines and has two compounds for hepatitis in clinical trials. The company employs 530 people worldwide and has a market capitalization of approximately €295 million (about $374 million).

FDA Grants CLIA Waiver For POC Lead Screening Test

The FDA has granted the application to categorize the new LeadCare II blood lead test system as waived under the Clinical Laboratory Improvement Amendment (CLIA), permitting widespread distribution to the approximately 115,000 nontraditional laboratory sites that have a CLIA waiver certificate.

Manufactured by ESA Biosciences (Chelmsford, MA), a subsidiary of Magellan Biosciences, the point-of-care test can screen children and adults for harmful levels of lead, using a finger stick or venous whole blood sample. Quantitative blood-lead results are available within three minutes. Blood-lead values that exceed the 10 milligrams per deciliter threshold used to indicate lead poisoning need to be confirmed with another laboratory method.



The LeadCare II blood testing system

The FDA-cleared LeadCare II system was classified as a moderate complexity test and is reimbursable under CPT code 83655, for which the national limit is $16.91. According to a company representative, the LeadCare II analyzer is priced at $2,200, with the test kit and control retailing for $348 and $43, respectively. ESA's original LeadCare system is the most widely used lead screening system in the world.

The Centers for Disease Control (CDC) estimates that every year more than 300,000 children under age 6 have blood levels that exceed the threshold used to indicate lead poisoning, a condition that has been linked to learning disabilities and developmental delays. According to the American Academy of Pediatrics (AAP), one out of four homes with children under age six has lead contamination. The CDC and AAP have issued recommendations for screening children at ages one and two who live in high-risk homes.

POLs Shifting Away From Non-Waived Testing

Physician office laboratories (POLs), which were responsible for 8% of the total number of reportable test results in the United States in 2005, generally perform less complex tests than hospital or independent laboratories. These tests include dipstick/tablet urinalysis, fecal occult blood, and urine pregnancy exams. Reimbursement for these types of tests is approximately 30% to 45% lower than for the typical text mix at hospitals or independent labs.

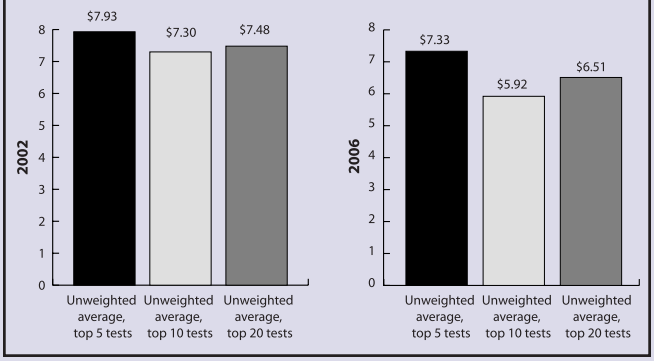
Twenty Most Common Laboratory Tests Offered at Family Physician Offices

Test	% Performing Test In-Office	CPT Code	Fee*
Dipstick/tablet urinalysis	97.1%	81002	$3.57
Fecal occult blood	92.1	82270	4.54
Urine pregnancy test	86.7	81025	8.84
Rapid strep (direct antigen)	83.7	87880	16.76
Vaginal smear/wet mount	79.0	87210	5.96
Glucose, using a waived instrument	69.3	82962	3.27
Urine microscopic exam	61.1	81015	4.24
Glucose, visual whole blood dipstick	39.5	82948	4.43
Infectious mononucleosis screen	38.5	86308	7.23
Hemoglobin by HemoCue (waived method)	33.9	85018	3.31
Prothrombin time	31.6	85610	5.49
Hemoglobin (automated non-waived method)	26.3	83036	13.56
CBC	27.8	85025	10.86
Spun microhematocrit (waived method)	27.3	85013	3.31
Hematocrit (automated, non-waived method)	26.3	85014	3.31
Differential (automated)	25.4	85004	9.04
Cholesterol	19.4	82465	6.08
Triglycerides	18.7	84478	8.04
Glucose (non-waived method)	18.5	82947	5.48
HDL cholesterol	18.5	83718	11.44
Unweighted average, top 5 tests	7.33		
Unweighted average, top 10 tests	5.92		
Unweighted average, top 20 tests	6.51		

*Medicare's national payment limitation amount, or fee cap, for 2006
Source: American Academy of Family Physicians, Practice Profile II Survey, May 2005; the American Medical Association; and CMS

Washington G-2 Reports estimates that POLs will comprise about 5%, or $2.5 billion, of the total $48.5 billion expected to be generated by all laboratories in the United States in 2006. G-2 also estimates that total revenue from POLs, despite a regular increase from 2000 to 2003, has begun a slight, but regular, decline consistent with the overall lack of growth in the area of POLs in comparison to the overall growth in CLIA-certified laboratories. Since 2000, the total number of CLIA-certified laboratories has grown 15.3% from 170,904 to 196,973. Although POLs have also grown from 95,874 in 2000 to 106,528 in 2006, they have grown at only 11.1%.

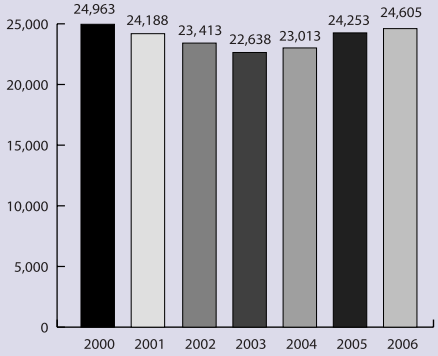
Unweighted Average Medicare Reimbursement for the 10 Most Common POL Tests, 2002 vs. 2006



The three most common (CLIA-waived and non-waived) tests performed at POLs are dipstick/tablet urinalysis, fecal occult blood, and urine pregnancy test, according to a survey of family practice offices conducted by the American Academy of Family Physicians in 2005. Among the 20 most common tests performed, the unweighted average Medicare reimbursement is $6.51. This is in dramatic comparison to the unweighted average Medicare reimbursement of the 20 most commonly performed tests in 2002, which

was $7.48. This is a $0.97 drop on average, or nearly 13%. That is less than half of the average that Quest Diagnostics and LabCorp receive per test ($14.10 per billable test) across all payers and approximately 40% of the $11.03 per billable test reported by hospital laboratories.

Total Number of Non-Waived POLs*, 2000-2006



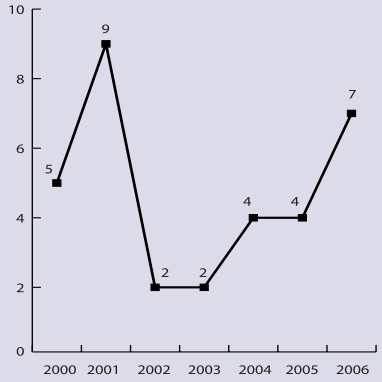
*Certified for moderate and/or high-complexity testing
Source: CMS

According to data from the CMS, there were 116,242 POLs operating in the United States by June 2006. Of these, 91,637 were certified only to perform waived testing and/or provider performed microscopy (PPM). Some 24,605 were certified to perform non-waived tests, i.e., testing of moderate and high complexity.

Why Not Non-Waived Testing?

There are several factors causing POLs to shift away from the non-waived category. The principle factor is the increased difficulty in meeting CLIA rules and regulations. On April 24, 2003, CLIA regulations required end-users to perform "method validation" before using a new non-waived test on patients. This not only requires more time and effort on the part of the POL, but generally requires a more sophisticated level of training and expertise on the part of laboratory personnel.

Number of New Tests Granted CLIA-Waived Status, 2000-2006



Source: Washington G-2 Reports from FDA files

Non-waived laboratories are also subject to routine inspections and/or proficiency testing. They must also pay volume-dependent fees every two years that range from several hundred dollars to several thousand dollars. Compare this to waived laboratories, which are not subject to inspections or proficiency testing. Their CLIA certificate only costs $150 every two years.

Another factor is that manufacturers of non-waived laboratory test procedures and equipment have declined, in general, to train POL laboratory personnel in validation issues or to write or set-up test policies and standard operating procedures.

CLIA-Waived Testing

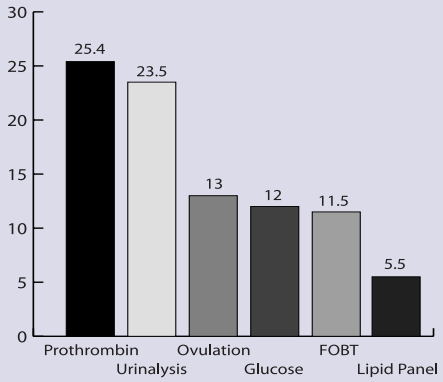
The highest volume waived tests are prothrombin (25.4 million tests/year), urinalysis (23.5 million tests/year), ovulation (13 million tests/year), glucose (12 mil-

Important New Waived Tests

Analyte	*Total U.S. Manufacturer*	*Typical Test Volume*	*Estimated Reimbursement*	*U.S. Market*
BNP	Biosite	15M	$40-60	$750M
Lithium	Akers Laboratories	12M	$10-20	$180M
TSH	ThyroTec	40M	$20-40	$1,200M
HIV 1/2	OraSure	17M	$15-25	$340M

Source: *DTTR*

High-Volume Waived Tests (millions)



Source: *DTTR*; CodeMap based on 2003 Medicare Part B claims data

lion tests/year), FOBT (11.5 million tests/year), and the lipid panel (5.5 million tests/year). CLIA-waived tests represent about $1 billion in annual laboratory testing revenue and, according to Charles Root, Ph.D., president of the consulting firm CodeMap (Barrington, IL), is expected to grow more than 20% a year.

BNP (B-TYPE NATRIURETIC PEPTIDE) TESTING: BNP testing is used to diagnose and assess patients with symptoms of heart failure. Since 2002, BNP is the fastest-growing test in the laboratory industry and is estimated to continue growing by approximately 20% per year.

At-a-glance

Cartridge cost: Approximately $20
CPT Code: 83880
Medicare Reimbursement: $47.43
Competition: Abbott i-stat

Manufactured by Biosite (San Diego, CA), the Triage BNP Test is a handheld analyzer utilizing a disposable cartridge. It gives results based on a few drops of blood within 15 minutes.

LITHIUM: Blood lithium levels are monitored by psychiatrists in patients prescribed lithium. Lithium is used for the treatment of a variety of manic depressive disorders, including bipolar. New patients are monitored at least every two weeks until levels are stabilized and typically once a month afterward.

At-a-glance

Analyzer cost: $399
Test cost: Approximately $11/test
CPT Code: 80178
Medicare Reimbursement national limit: $9.24 per test
Average reimbursement: $10-20 per test

Manufactured by Akers Biosciences (Thorofare, NJ), the InstaRead Lithium Test allowed lithium levels to be monitored, using fingerstick blood samples with results in two minutes.

THYROID STIMULATING HORMONE (TSH): TSH is used to screen for hypothyroidism. The Thyrotest device, manufactured by ThyroTec (Honey Brook, PA), is the first TSH test to receive waived status and provides a qualitative "yes" or "no" answer for above normal levels of TSH. It is disposable, is about the size of a credit-card, and provides results in 10 minutes from two drops of whole blood from a fingerstick.

At-a-glance

Cost: Package of 20 tests each for a list price of $299, or $14.95/test
CPT Code: 84443
Average reimbursement: $20-40
Medicare Part B reimbursement national limit: $23.47

HIV Testing: The OraQuick device, manufactured by OraSure Technologies (Bethlehem, PA) was the first HIV-1 antibody test for use on oral fluid, fingerstick, or venipuncture samples to receive waived status. OraQuick is about the size of a toothbrush, is disposable, and provides results in 20 minutes. Its market is physician offices and public health clinics.

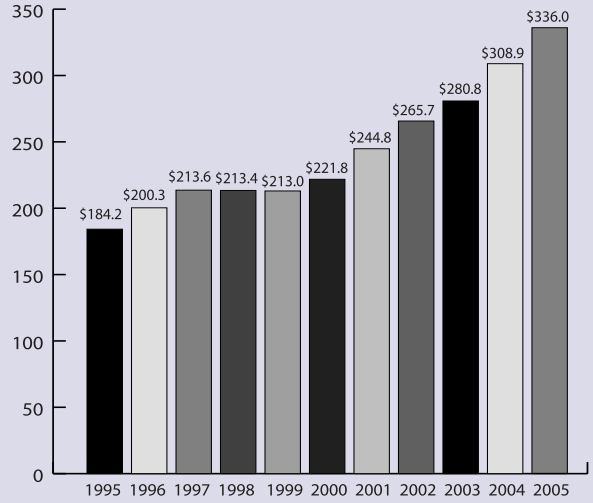
At-a-glance

Cost: Approximately $11/test to physician offices
Average reimbursement: $15-25
Medicare Part B reimbursement national limit: $19.17/test

Medicare Reimbursement: How Low Can It Go?

Last year, 42.5 million people were enrolled in Medicare, or about 14% of the U.S. population. By 2031, when the baby boomer generation will be completely enrolled, there are expected to be 77 million people covered by the program. Over the last 10 years, expenditures have grown by an average of 5.8% a year, from $184.2 billion in 1995 to $336 billion in 2005.

Total Medicare Expenditures, 1995-2005 ($BB)



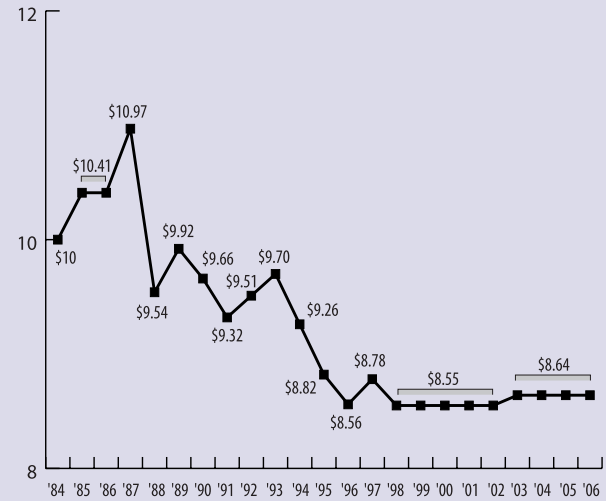
Source: CMS

Reimbursement Pressure

Medicare has placed significant reimbursement pressure on the U.S. clinical laboratory industry since the mid-1980s. In 1984, Congress imposed a fee schedule on clinical laboratory service reimbursement performed on patients covered under Part B. In 1984, local laboratory fee schedules were set at 60% of the prevailing rate (75th percentile) for each applicable lab test in each carrier area for services performed in physician offices and independent labs and for hospital-referred patients. Hospital outpatient laboratory service rates were initially set at 62%, then later reduced to 60% except for sole community hospitals.

Congress imposed a fee cap (Medicare maximum allowable), or national limitation amount, on most tests subject to local laboratory fee schedules in 1986. The cap was set at 115% of the national median for each affected test. Between 1986 and 1996, this cap was decreased to 76% and then, under the 1997 Balanced Budget Act, was whittled down to 74%. From 1998 to 2002, a freeze on inflation updates to the lab fee schedule was put in place.

Effect of Medicare Laboratory Fee Schedule Changes on a $10 Test



Source: Washington G-2 Reports

An exception was made in the Benefits Improvement and Protection Act of 2000. Congress approved setting the cap at 100% of the national median for tests for which caps were established on or after Jan 1, 2001. CMS, however, has utilized this authority for 12 diagnostic/screening Pap smear codes. In 2003, Medicare placed a 1.1% inflation update. The Medicare Modernization Act cancelled a scheduled 2.6% inflation update for 2004 and enacted a five-year freeze from 2004 to 2008.

The table at left shows the effect of Part B lab fee schedule increases and decreases on a hypothetical test reimbursed at $10.00 in 1984. Since 1984 all tests have been subject to the same changes, except for specific automated tests and urinalysis, which were reduced by an additional 8.3% in 1988. As a result, in the last 20 years the Part B reimbursement for our hypothetical test has dropped to $8.64.

The table at right probes the Part B reimbursement changes to a hypothetical $10 lab test. Part B reimbursement has declined by an average of 1% a year over the past 20 years. If the Part B fee schedule had instead been given an annual inflation update of 3% since 1984, the hypothetical $10 test would now be reimbursed at $18.91. Instead, it is reimbursed at $8.64.

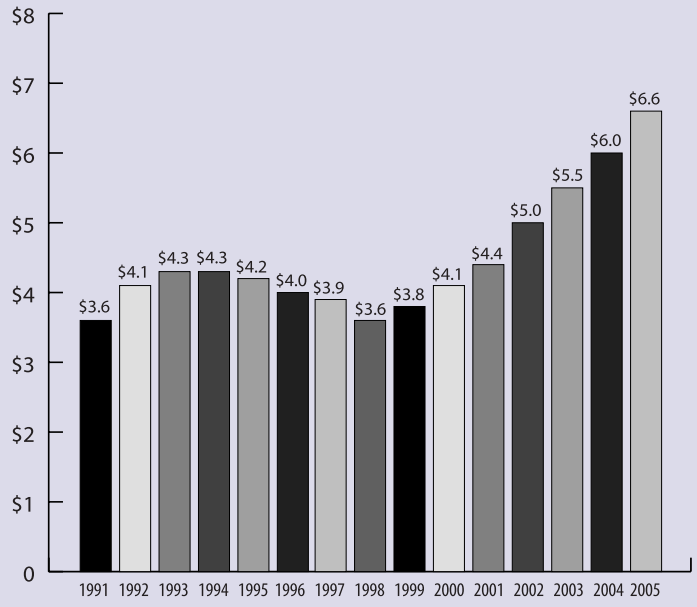
Changes in Medicare Laboratory Fee Schedule for a $10 Test

1984	Payment established for CPT code based on 60% of median charge	$10.00
1985	4.1% increase in all fees	10.41
1986	National limitations established at 115% of median payment	10.41
1987	5.4% increase in all fees	10.97
1988	Caps reduced to 100% of median	9.54
1989	4% increase in all fees	9.92
1990	4.7% increase in all fees; caps reduced to 93% of media	9.66
1991	2% increase in all fees; caps reduced to 88% of median	9.32
1992	2% increase in all fees	9.51
1993	2% increase in all fees	9.70
1994	Caps reduced to 84% of median	9.26
1995	Caps reduced to 80% of median	8.82
1996	2.7% increase in all fees; caps reduced to 76% of median	8.56
1997	2.6% increase in all fees	8.78
1998	Caps reduced to 74% of median	8.55
1999	No changes	8.55
2000	No changes	8.55
2001	No changes	8.55
2002	No changes	8.55
2003	1.1% increase in all fees	8.64
2004	No changes	8.64
2005	No changes	8.64
2006	No changes	8.64
2016	Assuming 3% annual update since 1984 (22 years)	18.91

Medicare Part B Spending Trends

Medicare Part B spending on clinical laboratory services continues to grow dramatically. The CMS's 2006 Medicare Trustees Report indicates that Part B laboratory spending increased by 8.7% to $6.561 billion in 2005.

Part B Spending on Clinical Laboratory Services, 1991-2005 ($BB)



Note: Includes all part B spending on lab services, including independent lab, hospital outpatient/outreach, and physician office labs. Source: 2006 Medicare Trustees Report

Part B lab spending declined through most of the 1990s, but has shown significant growth over the past seven years. From 1998 to 2005, Part B lab spending increased at an average rate of 8.8% annually. Over the same period, total Medicare Part B spending rose by 10.5% per year to hit $149.1 billion, or 1.25% of the gross domestic product. Total Medicare program expenditures increased by 10.5% annually to reach $336.3 billion.

Individual Laboratory Procedures

The table on page 9, provides the top 25 laboratory procedures ranked in order of allowed charges for independent labs, POLs, and other labs submitting claims to Medicare Part B carriers in 2005. These procedures accounted for approximately 33% of the total lab allowed charges in 2005.

Allowed Charges for Top 25 Clinical Laboratory Procedures, 2005

Rank	CPT Code	Procedure Name	Allowed Charges	Average Allowed Charges
1	85025	Complete blood count (CBC)	$317,878,238	10.86
2	84443	Thyroid stim hormone (TSH)	287,571,424	23.47
3	80061	Lipid panel (4 tests)	281,680,988	0.0*
4	80053	Comprehensive metabolic panel (14 T)	262,066,867	14.77
5	83036	Hemoglobin;glycated	138,077,766	13.56
6	83970	Parathyroid hormone	125,187,370	57.67
7	85610	Prothrombin time	114,148,110	5.49
8	80048	Basic metabolic panel (8 tests)	98,082,872	11.83
9	84153	Prostate specific antigen (PSA)	83,564,018	25.70
10	82728	Ferritin	53,564,183	19.03
11	87086	Urine bacterial culture	40,794,993	11.28
12	82607	Vitamin B12	38,030,441	21.06
13	83550	Iron binding capacity	34,923,350	12.21
14	83540	Iron	34,835,855	9.05
15	84439	Thyrosine, free	33,721,703	12.60
16	80076	Hepatic function	33,008,844	11.42
17	81000	Urinalysis, automated	28,922,391	4.43
18	85027	Complete blood count (CBC, auto)	26,448,725	9.04
19	87340	Hepatitis B surface antigen	24,935,570	14.43
20	82746	Folic acid	24,308,373	20.54
21	81001	Urinalysis	23,289,827	4.43
22	84436	Thyroxine, total	22,330,529	9.61
23	87088	Urine bacterial culture	21,618,222	11.31
24	83721	LDL cholesterol	21,552,798	13.33
25	81002	Urinalysis nonauto w/o scope	15,596,358	3.57

Note: Data include Medicare Part B information on independent, physician office, and other labs, but not hospital outpatient/outreach labs that bill fiscal intermediaries.
*See Coverage for Cholesterol Screening, below. Source: CMS

tNOX Testing Shows Promise For Early Cancer Detection

The tumor-associated plasma membrane-associated NADH oxidase (tNOX) garnered a lot of buzz at the first meeting on Molecular Diagnostics in Cancer Therapeutic Development, organized by the American Association for Cancer Research (AACR). In studies presented at the conference, testing for tNOX showed promise as a robust screening procedure for lung and prostate cancer.

tNOX, an overactive form of an enzyme that normal cells express only when dividing, is assumed to be vital for the growth of cancer cells.

Researchers at Purdue University looked to tNOX for an accurate way to screen for lung cancer in smokers. The researchers evaluated four different protocols to determine tNOX levels in the blood of 421 subjects with and without lung cancer, which is still the top cancer killer in the United States. Two of the protocols used high-throughput screening techniques and gave a low incidence of false-positive diagnoses of lung cancer. The other protocols, which used two newly developed antibodies against tNOX, provided a definitive indication of lung cancer. In the 25 healthy individuals, the test had no false positives. In lung cancers, 103 of the 104 patients were positive for tNOX. In smokers older than 40 years of age, 12% were positive, which is about the normal incidence picked up with high-resolution scanning techniques.

tNOX testing could serve as a screening tool for the early detection of lung cancer, with those who test positive receiving follow-up testing. A tNOX test would also be faster and cheaper than current diagnostic methods. "This test is structured with the antibody we're using to be specific for lung cancer in one form or another," said Purdue University professor Dorothy Morre, Ph.D., one of the study's authors. "It's a specific diagnosis, and it also distinguishes between non-small and small cell lung cancer." Further studies will seek to correlate tNOX antibody test results with standard procedures for detecting early stage lung cancer, such as high-resolution CT and physician examinations.

The tNOX protein is also showing promise as a way to assess the presence and the extent of prostate cancer. A study presented at the AACR meeting shows that it may prove to be more reliable than the standard prostate specific antigen (PSA) test, which gives false-positive readings at least 20% of the time, and the often unreliable digital rectal exam.

Researchers studied patients in a phase II clinical trial of phenoxodiol in late-stage metastatic prostate cancer. Blood samples taken at various stages of the 12-week drug treatment were analyzed for tNOX and compared to PSA blood levels taken at the same times. Of 19 patients in the trial, nine who had prostate cancer that was continuing to grow based on PSA levels showed on average a 60% greater amount of circulating tNOX protein compared to those patients who had stable or falling PSA levels.

"It's the first demonstration that we have, assuming that PSA levels indicate major tumor burden in some fashion, that tNOX levels also reflect tumor burden during and after therapy for prostate cancer," said D. James Morre, Ph.D., the study's lead author. "We think our marker may be more closely aligned to tumor burden than PSA. It looks like it stands a better chance of being proportional to tumor burden and may be more reliable. It seems to be more uniform in terms of disease severity."

According to Morre, tNOX will probably find greater use in estimating the amount of cancer, rather than in detection, and could be another useful marker for monitoring an individual's response to therapy. Further studies will aim to link tNOX and PSA levels as estimates of tumor burden and to monitor responses to therapy of patients with late-stage metastatic prostate cancer.

IVD Stocks Rise 4%; Third Wave Jumps 51%

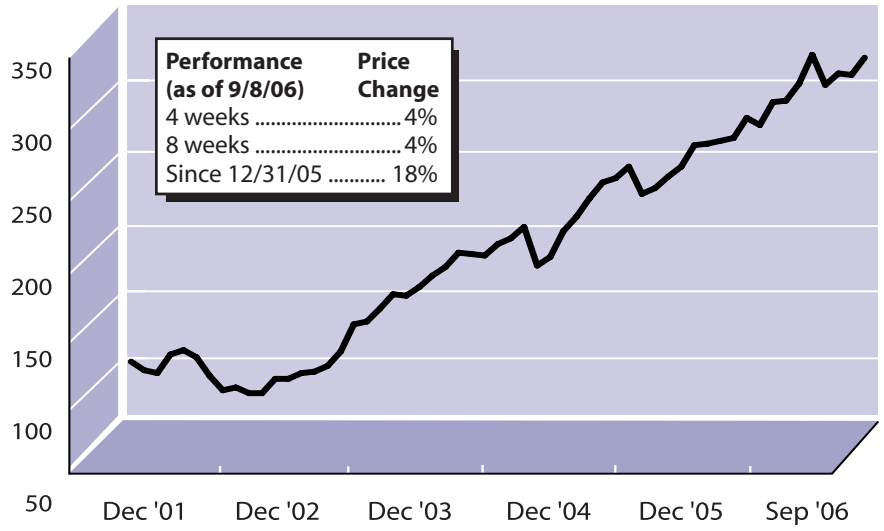
The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 4% in the four weeks ended September 8, with 12 stocks up in price, eight down, and one unchanged. Year to date, the G-2 index is up 18%, while the Nasdaq is down 2%, and the S&P 500 is down 4%.

Third Wave (Madison, WI) soared 51% to $4.48 per share for a market capitalization of $191.4 million. The company has begun the clinical trial for two human papillomavirus (HPV) tests, keeping on track its plan to apply for FDA approval for those products next year. One of the tests screens for the presence of 14 high-risk types of HPV, while the other is a genotyping test to detect two specific types of the virus, HPV-16 and 18, that cause about 70% of cervical cancer cases. In the second quarter, Third Wave narrowed its net loss on higher revenue from core molecular diagnostic products, with total revenue for the quarter up more than 15% to $6.8 million compared to $5.8 million during the same period last year.

Despite recently posting a second-quarter loss of $4 million amid lower gross margins and higher costs, point-of-care test maker **Quidel** (San Diego, CA) was up 31% to $11.34 for a market capitalization of $402.5 million. The company just received FDA 510(k) clearance for its new QuickVue respiratory syncytial virus (RSV) test. Quidel also recently announced that its CFO, Paul E. Landers, will retire from the company in 2007.

Meanwhile, **OraSure** (San Francisco, CA), maker of oral fluid-based diagnostics, plummeted 27% to $6.75 for a market capitalization of $331.5 million. Although the $17.6 million in revenue for the second quarter exceeded analyst expectations, net income was crippled by stock-option expenses and income tax charges. The company also reduced its outlook for 2006, citing lowered forecasts by the distributor for its cryosurgery products and mediocre performance of its European distributor.

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.

	Price	% Chg
UP		
Abbott Labs	$48.90	4%
Beckman Coulter	53.76	4
Becton Dickinson	68.60	4
Bio-Rad	71.60	4
Biosite	45.48	9
Cholestech	13.02	16
Cytyc	24.48	2
Dade	41.10	1
Immucor	21.50	7
Meridian	22.00	7
Quidel	11.34	31
Third Wave	4.48	51
UNCHANGED		
Johnson & Johnson	63.59	0
DOWN		
Abaxis	22.32	-4
Affymetrix	19.58	-2
Bayer	48.37	-1
Digene	40.39	-2
Gen-Probe	47.01	-11
Inverness Medical	32.51	-1
OraSure	6.75	-27
Ventana	44.02	-4

G-2 Insider

Announcing Washington G-2/IOMA's Inaugural LabCompete Conference: Strategies for 2007 and Beyond, December 6 to 8, 2006, at the Sheraton Wild Horse Pass Resort and Spa in Chandler, Arizona.

Some LabCompete Highlights:

- ❑ Keynote Address: Where Is Your Lab Going Now That It's Faced With a Duopoly? David Nichols, president of the Nichols Management Group
- ❑ Charles C. Miraglia, M.D., president and CEO, and William Daniel Follas, executive vice president Strategic Operations, PA Labs LLC, analyze the financial impact of offering esoteric tests
- ❑ Michael Finnerty, partner, Kaufman Hall, discusses Joint Ventures, Divestitures and Acquisitions—The Next Competitive Strategies for Hospitals and Labs
- ❑ Philip Chen, M.D., Ph.D., president, Cognoscenti, helps you tackle your most pressing questions on how to develop a third millennium outreach environment
- ❑ Pathology Associates Medical Laboratories shows you how to innovate with a multifaceted approach to Web connectivity strategies and CRM initiatives
- ❑ Gregory Clark, Ph.D., DABCC, chief operating officer, Oregon Medical Laboratories, builds the case for automation. Ready for a radical change?
- ❑ Ted Hull, president and CEO, Genova Diagnostics—How one lab is taking advantage of the consumer's interest in optimal health. Connect with your consumers and develop wellness and prevention services

For complete program information and a brochure go to g2reports.com

Company References

AACR 215-440-7228

Abbott 847-937-6100

Cytyc 508-263-2900

ESA Biosciences 978-250-7000

Innogenetics 32-9-329-13-29

Iris 818-709-1244

LabCorp 336-584-5171

OraSure 610-882-1820

Quidel 800-874-1517

Rubicor 877-424-6779

Safeguard Scientifics 610-293-0600

Third Wave 888-898-2357

Ventana Medical Systems 520-887-2155

DTTR Subscription Order or Renewal Form

❑ **YES**, enter my one-year subscription to the ***Diagnostic Testing & Technology Report (DTTR)*** at the rate of $419/yr. Subscription includes the ***DTTR*** newsletter and electronic access to the current and all back issues at *www.ioma.com/g2reports/issues/DTTR*. Subscribers outside the U.S. add $50 postal.*

❑ I would like to save $174 with a 2-year subscription to ***DTTR*** for $664.*

❑ **YES**, I would also like to order ***Lab Industry Strategic Outlook 2005: Market Trends & Analysis*** for $995 ($795 for Washington G-2 Reports subscribers). (LR37)

Please Choose One:

❑ Check enclosed (payable to Washington G-2 Reports)

❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Ordered by:

Name _____

Title _____

Company _____

Address _____

City _____ St _____ ZIP _____

Phone _____ Fax _____

e-mail address _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

Return to:
Washington G-2 Reports,
3 Park Avenue, 30th Floor,
New York, NY 10016-5902
Tel: (212) 629-3679
Website: *www.g2reports.com*

For fastest service:
Call (212) 629-3679
or fax credit card order
to (212) 564-0465

DTTR 10/06

 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.

Stephanie Murg, Managing Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Group Publisher; Joe Bremner, President.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 2.