

LABORATORY

INDUSTRY REPORT®



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September 23-25, 2009
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G-2 Reports March Survey Finds Test Volume Growth Slows to Less Than 1% During First Quarter; Lab Directors Expect 1.4% Growth for 2009

The recession is at least partly to blame for slowing testing growth in the first quarter of 2009, with the average volume growth clocking in at only 0.7 percent due to economic conditions, according to results from more than 100 laboratories in the recent *Washington G-2 Reports' March Survey on Lab Trends: The Effects of the Recession on Test Volume*. For full year 2009, respondents reported an overall average expected volume growth of 1.4 percent—well below the industry's long-term annual volume growth trend of 2 percent to 3 percent.

When asked about the effect of the recession on test volumes for the first two months of 2009, respondents from hospital/health system

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H1N1 Pandemic Threat, Health Care Overhaul Underscore Key National Priorities for Labs

Lab industry leaders sounded off on conflicting messages from the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) on testing protocols related to the H1N1 flu outbreak, as well as the CDC's refusal to distribute official testing kits to the nation's largest testing providers due to intellectual property concerns, at the recent American Clinical Laboratory Association's (ACLA) annual meeting, held May 6 and 7 in Washington, D.C.

The H1N1 outbreak is occurring while Congressional lawmakers design comprehensive health care reform legislation that is likely to cost between \$1 trillion and \$3 trillion over the next 10 years. This hefty price tag will necessitate deep spending reductions, and the lab industry needs to protect itself from lab fee schedule and physician reimbursement cuts by pressing Congress on the value of lab services, emphasized both industry and congressional leaders at the ACLA meeting.

For more on this story, please read "Inside the Lab Industry," on pp. 5-8. 



■ G-2 REPORTS MARCH RECESSION SURVEY, from page 1

labs reported almost no gain (0.1 percent), while independent labs noted a 2.2 percent growth (see Table 1).

However, these figures are up from test volume growth reported by respondents for the last three months of 2008. Even though it's not a direct comparison given

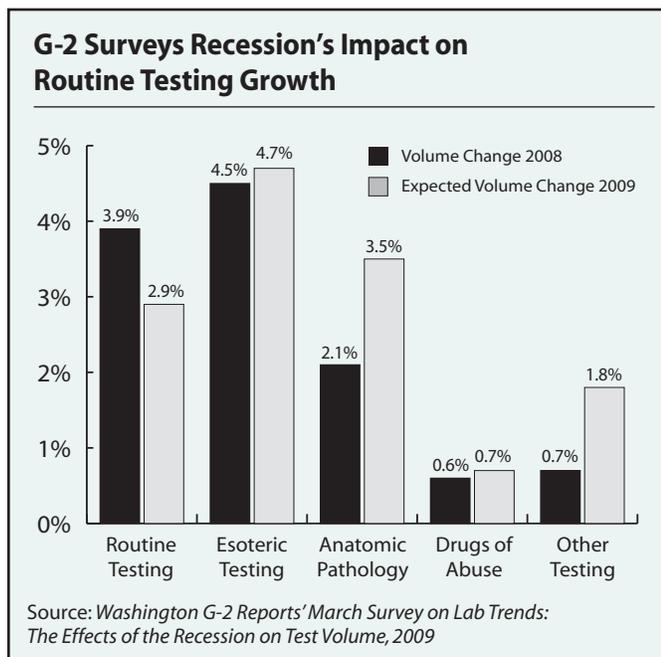
Table 1

Effects of Recession on Test Volumes in First Two Months of 2009 (Compared to Same Time Period in 2008), by Lab Type				
	<i>Increase</i>	<i>Decrease</i>	<i>No change</i>	<i>Overall</i>
Hospital/Health System Lab	38.5%	38.5%	23.1%	100.0%
<i>Average Change (%)</i>	8.9	-9.0	-	0.1
Independent Lab	37.5	34.4	28.1	100.0
<i>Average Change (%)</i>	16.0	-11.0	-	2.2
Pathology Group	16.7	66.7	16.7	100.0
<i>Average Change (%)</i>	2.0	-3.3	-	-1.6
Other	37.5	37.5	25.0	100.0
<i>Average Change (%)</i>	8.3	-5.0	-	2.1
Overall	36.8	38.4	24.8	100.0
<i>Average Change (%)</i>	10.5	-8.9	-	0.7

the different lengths of time, it's interesting to note that respondents from independent labs reported increased volume growth of 2.2 percent early in 2009, compared to 0.9 percent during the final three months of 2008. For hospital/health system labs, the end of 2008's volume growth of 0.6 percent was slightly ahead of early 2009's volume growth of 0.1 percent.

Routine Testing Volume Growth Expected to Be Down

While respondents reported the early 2009 overall average volume growth of 0.7 percent, respondents expected full year overall average volume growth to climb to 1.4 percent—again, far below the benchmark year growth rate of 2 percent to 3 percent. Hospital/health system labs reported an expected overall growth rate of 0.7 percent, while independent labs reported an expected growth rate of 4.8 percent.



The G-2 survey also asked respondents about the average volume growth based on test category for 2008, as well as their expected growth rates for 2009 (see figure). According to the results, it appears as if respondents expect all test categories to grow, including routine testing. But while this testing grew a surprising 3.9 percent last year, it's only expected to grow 2.9 percent this year, reported the respondents. Anatomic pathology is expected to grow the most—3.5 percent this year compared to 2.1 percent in 2008. Esoteric testing is expected to grow 4.7 percent this year, compared to 4.5 percent last year. Drugs-of-abuse testing—which is closely

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CAP, ASCP Join ACLU Suit Over Breast Cancer Gene Patents

The College of American Pathologists (CAP) and the American Society for Clinical Pathology (ASCP) has joined the American Civil Liberties Union (ACLU; New York City) and the Public Patent Foundation (New York City) in a lawsuit against U.S. Patent and Trademark Office, Myriad Genetics (Salt Lake City), and directors of the University of Utah Research Foundation, charging that patents on BRCA1 and BRCA2, genes associated with hereditary breast and ovarian cancer, stifle valuable medical research. The suit is the first to apply the First Amendment to a gene patent challenge.

The lawsuit was filed on May 12 in the United States District Court in the Southern District of New York on May 12. The lawsuit's long list of plaintiffs includes women's health groups, individual women, and scientific associations, such as the Association for Molecular Pathology and the American College of Medical Genetics. The lawsuit argues that the patents on these genes are unconstitutional and should be invalidated because genes are "products of nature." Approximately 20 percent of all human genes are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, and asthma.

Myriad's gene patents give the Salt Lake City-based company exclusive rights to perform diagnostic tests on the BRCA1 and BRCA2 genes. It does so through its flagship BRCAAnalysis test, which assesses a woman's risk of developing breast or ovarian cancer based on detection of BRCA1 and BRCA2 gene mutations. The highly profitable test is performed in Myriad's CLIA-certified laboratory and costs approximately \$3,200, with operating margins of nearly 50 percent. The test is reimbursed by most insurance providers. According to the ACLU lawsuit, Myriad's control over BRCA1 and BRCA2 hampers clinical diagnosis and serves as a disincentive for research because Myriad not only has the right to enforce its patents against other entities but also has the rights to future mutations discovered on the BRCA2 gene. 🏛️

CMS Denies Reimbursement for Gene-Based Warfarin Testing; Proposes Clinical Trial Coverage

Because the Centers for Medicare & Medicaid Services (CMS) does not believe that current available evidence demonstrates that pharmacogenomic testing to predict warfarin responsiveness improves health outcomes in Medicare beneficiaries, the agency stated in a proposed decision memo that it would not provide coverage for Medicare beneficiaries for this testing. However, CMS said the available evidence on the effectiveness of the pharmacogenomic testing suggested that coverage with evidence development (CED) would be appropriate. Therefore, this testing would only be covered if the beneficiary were a candidate for anticoagulation therapy with the drug warfarin in the context of a randomized clinical trial that meets specific criteria.

In the proposed decision memo, CMS noted that the use of pharmacogenomic testing would be used to predict a patient's response to warfarin before the initial



tion of the drug. The agency said it would be a once-in-a-lifetime test, absent any reason to believe that the patient's personal genetic characteristics would change over time. Warfarin is a self-administered oral blood thinner and affects vitamin K dependent clotting factors. It has the trade name of Coumadin, but also is marketed by various manufacturers under different names.

There has been only one instance when CMS expanded Medicare coverage following data collection under CED. That occurred in April, when CMS expanded coverage of positron emission tomography (PET) scans for certain cancer treatments. 🏛️

Medicare Part B Lab Spending Up 3.3% to \$7.3 Billion in 2008

Medicare Part B spending on clinical laboratory services continues to increase, with 2008 spending totaling \$7.3 billion, an increase of over 3 percent from 2007 totals, according to the latest data from Centers for Medicare & Medicaid Services's *2009 Medicare Trustees Report*. The Medicare program covered a total of 45.2 million enrollees in 2008.

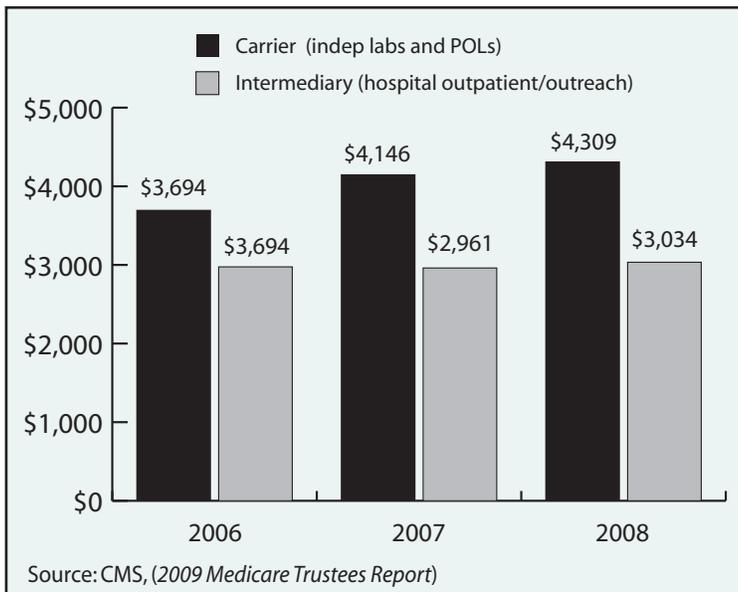
Total Medicare program spending increased by 8.4 percent to reach \$468 billion in 2008, as compared with \$431.7 billion in 2007. This means that Part B lab services spending made up 1.6 percent of the total Medicare spending for last year. Of the \$7.3 billion total for Part B lab services, 59 percent or \$4.3 billion was comprised of spending for lab-related carrier services—which include independent and physician office labs. This is an increase of 4 percent over 2007's total of \$4.1 billion. Forty-one percent—or \$3 billion—was from intermediary lab-related

services, which include hospital outpatient and outreach testing services. This represents an increase of 2.5 percent from 2007's total of \$2.9 billion.

For the intermediary services, spending per fee-for-service enrollee (FFS) for outpatient lab testing totaled \$88.37 in 2008, an increase of 2.2 percent over 2007's FFS amount of \$86.44. For the carrier services, FFS spending came in at \$130.92, up 7 percent from 2007's amount of \$121.86.

At approximately \$189 billion, total Part B spending was 1.3 percent of the gross domestic product (GDP) in 2008 and is projected to grow to about 4.5

percent by 2083. However, the report notes that this figure is understated as a result of the multiple years of physician payment reductions that are currently required under law, including the scheduled cut of 21.5 percent for 2010. If these reductions are implemented, the GDP spending rate could increase to 18 percent to 21 percent in 2015 and as much as 10 percent by 2030 and later. 🏛️



CDC Limits Lab Industry's Role in H1N1 Flu Diagnosis Due to IP, Reagent Supply Concerns

State and local public health laboratories across the United States were overwhelmed by testing demands related to the H1N1 influenza A outbreak—also called swine flu—in late April and early May. But the Centers for Disease Control and Prevention (CDC) would not send the nation's second largest diagnostic testing provider the "official" test kits the agency was using for sample submission due to intellectual property (IP) concerns, LabCorp's recently named chief medical officer, Mark Brecher, M.D., explained at a panel discussion during the American Clinical Laboratory Association's (ACLA) annual meeting, held May 6 and 7 in Washington, D.C.

There were also concerns about adequate reagent supplies for the official rRT-PCR swine flu panel diagnostic test kits that limited distribution. These kits were developed by the CDC and shipped to state and public health labs in early May, following an emergency use authorization (EUA) issued by the U.S. Food and Drug Administration (FDA) on April 27 in response to a request from CDC.

Because LabCorp and Quest Diagnostics are the nation's two largest test providers, their facilities would most likely have initial contact with infected patients, not just in this most recent outbreak but in any public health emergency. However, Brecher and other industry leaders on the panel complained that conflicting guidelines and messages from the CDC and the World Health Organization (WHO) created an atmosphere of chaos and confusion during the early days of the outbreak.

"It's clear that both the CDC and the FDA don't realize how medicine is practiced in this country," said Brecher. Most concerning was the fact that the CDC wouldn't send the official submission test kits to the large commercial labs to help offset the inability of the state and public health laboratories to deal with the surge demand for both staff and supplies. LabCorp officials were told by the CDC that they wouldn't send test kits to the big labs because of IP issues, but these test kits need to get out to the big labs that can get ramped up to help, he added.

A CDC spokesman declined to comment on the IP issues, commenting that the official diagnostic test kits were distributed to 95 labs in 50 states plus D.C. and Puerto Rico, as well as 237 labs in 107 countries outside of the United States. However, Rosemary Humes, the senior adviser for scientific affairs for the Association for Public Health Laboratories (APHL), told *LIR* that it is her understanding that the IP issues relate to the chemistry used in the tests,

"It's clear that both the CDC and the FDA don't realize how medicine is practiced in this country."

*— Mark Brecher, M.D.,
LabCorp CMO*

which is owned by Roche Diagnostics (Indianapolis) and licensed to Life Technologies (Carlsbad, Calif.), which was created from the November 2008 merger of Invitrogen Corporation and Applied Biosystems. “Using those tests in a public health sector has one set of IP requirements, but using them in a private sector has another,” she added. “It’s not clear if the intellectual property would be protected if used in a private lab.”

Surge Demand Taxes Public Labs

Demand for testing has quickly escalated both at the public health and commercial laboratories. According to the APHL, one jurisdiction with a daily capacity to test 200 specimens was reporting a backlog of 3,500 specimens in early May, with 1,000 specimens coming in daily. At the nation’s largest testing provider, Quest Diagnostics, some facilities saw demand for various influenza tests spike from a handful to hundreds daily, according to Lee H. Hilborne, M.D., the company’s medical director for the Southern California region, who also spoke at the ACLA flu panel. Many clients were calling Quest asking about testing protocol and what test to perform because they were also receiving conflicting messages from the CDC and WHO.

This surge demand is occurring at a time when many public health laboratories are facing significant economic challenges. Nationwide, the public health laboratory workforce has seen a decline of about 1,000—from 7,000 to 6,000—in recent months according to an APHL survey taken earlier this year for the first quarter of 2009. Public health laboratory budgets have also been slashed, resulting in mandatory furloughs and reduced funding for equipment and supplies. Based on preliminary data from the association’s second quarter survey, more budget cuts and staff reductions are expected this year.

While Humes said she couldn’t speak directly to the conversations between the CDC and the commercial labs, she elaborated on a few issues

that prevented the test kits from being distributed to commercial labs. “The FDA allowed the CDC to deploy the test kits under an emergency use authorization, or an EUA,” she explained. “Under this EUA, there were specific requirements about who could get them, what kind of qualifications the lab had to have, and in the emergency, trying to make sure private sector labs met those qualifications was difficult.”

Quest Diagnostics Develops H1N1 Flu Diagnostic Test

In mid-May, Quest announced the availability of a laboratory developed test to help identify patients infected with the novel H1N1 virus and differentiate patients infected with other seasonal influenza A strains. The test was developed by Quest’s infectious disease reference laboratory, Focus Diagnostics, which is based in Cypress, Calif. The real-time polymerase chain reaction (PCR) test was validated using clinical specimens submitted to its reference laboratory confirmed as positive for the novel H1N1 influenza virus by public health authorities. The test will be performed at the Cypress location in accordance with current public health guidelines, and the company indicates that expected turnaround time for reporting results is within 24 hours of receipt of specimen by the Focus Diagnostics laboratory.

There was also a concern about protecting the reagent supply, she added, to ensure that sufficient testing supplies were available to manage the public health event and monitor the spread of the disease. There are a limited number of reagent supplies—and not just the reagents that the CDC makes, but also for the PCR testing, the reagents and extraction kits made by the commercial companies. “There were a number of issues about why distribution of testing too broadly would not have been appropriate,” said Humes. “These kits were in demand all over the world, so trying to control testing and make sure testing was targeted to the people most in need was an important priority.”

Push to Insulate Labs From Funding Cuts to Pay for Reforms

Even though the pandemic fears are now somewhat subdued, the incident—and the promise of a future outbreak, maybe as soon as this fall—is an important opportunity to highlight the value of labs, said Quest’s Hilborne.

APHL’s Humes believes that the private sector can play an important role in screening out the worried well or people with other respiratory illnesses, as well as all of the acute care testing that accompanies a disease outbreak. “Using the flu tests that they currently use and ruling out the flu—especially in those early stage where everyone is demanding testing, yet most people don’t meet the definition for the outbreak, that’s an important role,” she explained. “And labs don’t need the subtype specific tests to do that, and getting the subtype specific test in the hands of every lab might not be the most effective use of resources.”

In addition to pandemic situations, the vital role of labs also needs to be made clear right now on Capitol Hill, where both the House and Senate are crafting massive health care reform bills that could cost between \$1 trillion to \$3 trillion over the next 10 years, in addition to the over \$600 billion down payment on reform that was included in the president’s latest budget. On May 13, House and Senate leaders pledged to have health care reform legislation to President Obama’s desk by the August recess. While this ambitious timeline might be unlikely, it is clear that Congress is prepared to push a reform measure through this year and that there will need to be massive spending cuts to pay for the reform. “This is moving fast,” said panelist Libby Mullin, president of the legislative consulting firm Mullin Strategies, who also spoke at the ACLA meeting. “You all need to take this very seriously as an industry.”

Both bills will feature a public plan that will provide coverage to the currently 46 million uninsured Americans. But exactly how this public plan will be designed—and how it will compete with the private plans—is likely to be the “crux of the debate,” said Rep. Diana DeGette (R-Colo.), at the ACLA meeting. DeGette is the chief deputy whip of the House, as well as vice chair of the Committee on Energy and Commerce, whose jurisdic-

tion includes health care. The trillions needed to fund these reform measures will most likely come from tax increases and deep spending cuts, and the lab industry needs to fight to insulate themselves from physician fee and lab fee schedule cuts to pay for the reform initiatives, she added.

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—Rosemary Humes, APHL

In addition, labs need to become part of the increased focus on prevention and wellness, said DeGette. Most prevention screenings are not reimbursed under Medicare, and there is not an industry presence on the regulatory body that writes the clinical guidelines that heavily influences reimbursement decisions—which is called the U.S. Preventive Services Task Force. Labs need to quantify the long-term cost savings associated

with prevention screenings and continue the struggle to get the value of lab tests across to the members of Congress, she explained.

Another change coming on the national level is the oversight of laboratory developed tests, reported Elizabeth Mansfield, Ph.D., the recently appointed FDA senior genomics and personalized medicine adviser, at the ACLA meeting. Mansfield hinted that increased oversight of these tests is coming in the near future. “We see that labs are developing tests as a way to avoid the FDA regulatory process,” she said. “Research use only is not a regulatory loophole put in place to allow device manufacturers to dodge the FDA.”

Another FDA official, Alberto Gutierrez, Ph.D., also addressed the issue of the oversight of laboratory developed tests. Gutierrez is the former acting director of the FDA’s Office of In Vitro Diagnostics (OIVD), following the retirement of Steve Gutman, M.D., and is now the deputy director for new product evaluation. Don St. Pierre is the OIVD’s current acting director.

“It’s become clear that having one regulation for IVDs [in vitro diagnostics] and another for laboratory developed tests is becoming less tenable,” said Gutierrez. It’s difficult to distinguish the companies that are setting up a CLIA to bypass regulation and other labs that are spending the necessary money to go through the regulatory process, he added.

“There’s a feeling out there that something needs to be done, and the FDA and this administration will address this problem, although how is yet to be seen,” continued Gutierrez. The form of oversight will depend on if it goes through the agency’s formal rulemaking process or by an act of Congress, which would mean less stakeholder input. “It could happen quickly if Congress decides to write a law, but if it’s accomplished by the FDA, then we will allow as much stakeholder input as possible,” he said. “The last thing we want to do is create havoc in public health.” 🏛️



PLUS Diagnostics Opens West Coast Lab; Plans to Launch Hematology/Oncology Testing Services This Year

Lakewood, N.J.-based anatomic pathology testing provider PLUS Diagnostics continues to expand with the opening of a 15,000 square foot West Coast facility in Orange County, Calif., which will serve as the foundation for the company's launch into hematology and oncology testing services by the end of this year. In addition, the company will expand its East Coast footprint when it moves to a new 25,000 square foot laboratory in Union, N.J. in August, which will triple its overall lab capacity, according to company CEO Doug Berg. There are also plans to expand the company's sales and marketing staff from the planned 30 by the end of 2009 to close to 50 by the end of 2010.

Last year, PLUS refined its platform business—genitourinary (GU) pathology—and entered the gastrointestinal (GI) pathology market, currently valued at between \$1 billion and \$1.5 billion in the United States. GU testing continues to drive most of the revenue for the company. Berg estimates that revenue will grow 100 percent this year to \$60 million, with about 80 percent coming from GU testing services and 20 percent from GI. By 2010, he expects revenue to grow to \$100 million, due in large part by the hematology and oncology testing offerings. "By 2010, we will have GU and GI under our belt, and no later than Jan. 1, 2010, we will have a full launch of hematology and oncology," he explained. 🏛️

Rosetta Genomics Sells Parkway Clinical Labs for \$2.5 Million in Management Buy-Out

The molecular diagnostic manufacturer and testing company Rosetta Genomics (Philadelphia; Rehovot, Israel) has sold Parkway Clinical Laboratories (Bensalem, Pa.) in a management buy-out agreement for \$2.5 million, to be paid out as a fixed percentage of revenues over six years. The chairman of the company will be Raza Bokhari, M.D., and the president will be Masood Haider, Ph.D., according to a Rosetta spokeswoman.

Rosetta acquired the 11,000 square feet CLIA-certified Parkway lab in July 2008 for \$1.9 million. The company then built a second laboratory in Philadelphia, which is called Rosetta Genomics Laboratories or RGL. The acquisition of Parkway helped RGL obtain CLIA certification, but now it seems that Parkway's core businesses—drugs-of-abuse and pre-employment drug testing—is not part of Rosetta's growth strategy. The company's microRNA tests will continue to be performed at RGL. 🏛️

■ G-2 REPORTS MARCH RECESSION SURVEY, *from page 2*

linked to hiring and employment trends—is expected to grow only 0.7 percent this year, an essentially flat growth rate compared to last year's 0.6 percent.

These results are in line with what lab industry insiders have been telling Washington G-2 Reports in recent months—that physician office visits are down, as well as routine testing and screenings. But utilization rates for testing that is



linked to chronic and related illnesses—in the form of anatomic pathology and esoteric testing—continues to climb. These results are also in line with some of the anecdotal comments solicited by the survey. When asked to describe specifically the impact that the recession was having on testing volumes, many respondents remarked that they were seeing a rise in self-pay and uninsured patients—as well as insured patients with higher deductibles. With the decline of coverage, many commented that patients are forgoing routine testings and screenings, which is causing volumes to decline. “Our lab is mainly affected because of less patient volumes,” remarked a lab director from a hospital or health system lab with an annual volume of over 750,000. “Emergency visits are up, but we are seeing more uninsured and self-pay patients. Patients coming to us are sicker and require more extensive testing, which is why the esoteric testing is increasing.”

Responding to the Recession

The G-2 survey also polled respondents about what actions they were currently taking to control costs (see Table 2). Reductions in travel, training, and other human resource-related costs were at the top of the list with 59.8 percent, followed by purchasing reductions or holds for reagents and supplies (respondents were allowed to choose multiple actions). Other popular approaches involve staffing: Almost 42 percent said they are holding the line on salary increases and almost 39 percent they are reducing staff. Two areas that don’t appear to be changing in response to the recession are pricing and test menus. Only 13 percent reported changing the test mix, and only 17 percent reported changing pricing.

Hiring and salary freezes were noted by many respondents from both independent and hospital /health system labs when asked to detail specifically how they were confronting the recession. “We have reduced overtime and are going to have to let some people go,” wrote a lab manager of an independent lab with an annual volume of over 22,000. An operations director at a hospital /health system lab responded, “We have not hired up to our budgeted FTEs. We have managed down overtime. We are sending staff home some days because of low need. Our productivity is up 4 percent over last year.”

Table 2

Actions Labs Are Taking in Response to the Recession	
Reduced our travel, training and other HR costs	59.8%
Reduced or put on hold equipment, reagent and supplies purchases	53.3
Held the line on salary increases	41.8
Reduced staffing/headcount	38.5
Changed our pricing	17.2
Changed our test mix	13.1
Other	22.1

Many respondents also noted an increased focus on customer service. “We are trying to closely monitor our expenses and our workloads and flex our staffing to those workloads,” noted a laboratory director from a hospital/health system lab with a volume of 440,000. “We are also delaying a couple of approved capital

equipment purchases, and we have postponed planned salary increases. And, last but not least, we are really pushing customer service and watching our outreach business to make sure we retain our current clients and find new opportunities to grow that business.” 



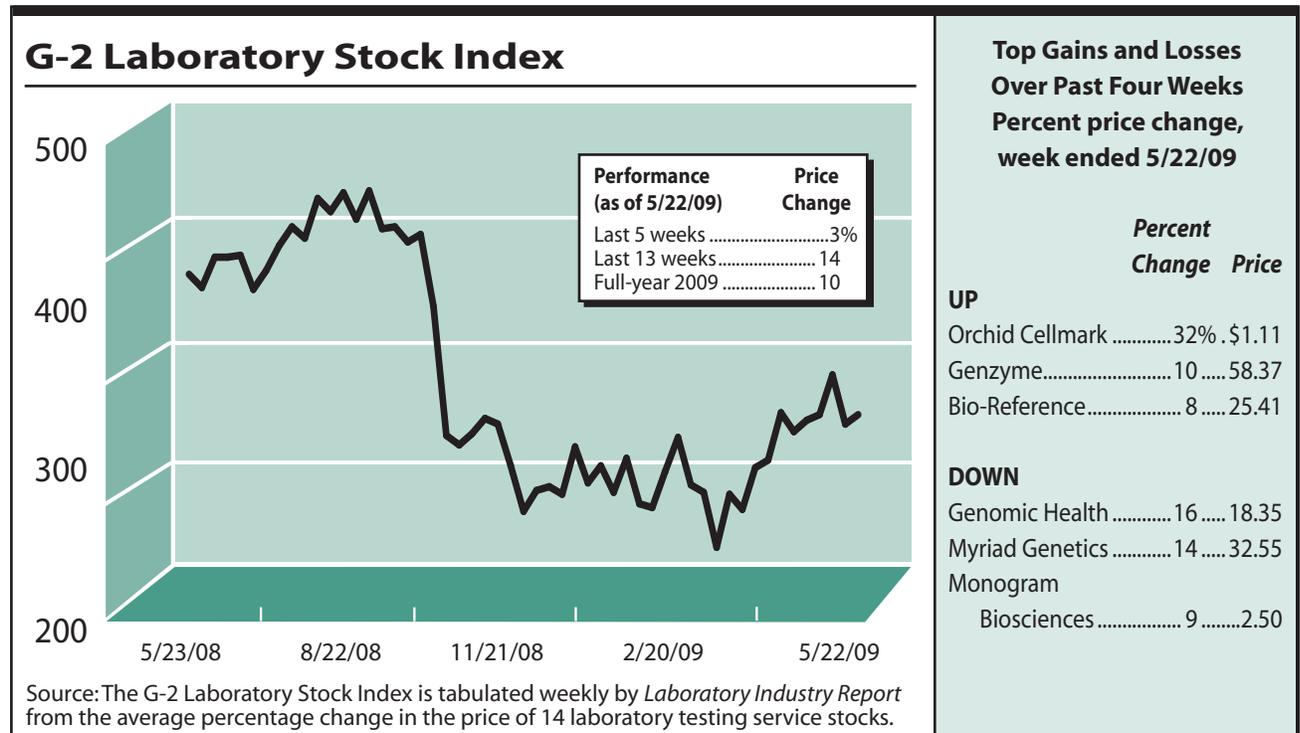
Lab Stocks Continue to Gather Strength; Up 3% Over Five Weeks, 10% for 2009

After a slight rebound in April, lab stocks continue to exhibit strength so far in May. Over the past five weeks, the 14 publicly traded labs tracked by the G-2 Reports Laboratory Stock Index are up 3 percent and 14 percent over the past 13 weeks for the week ended May 22, 2009. So far in 2009, the Index is up 10 percent. The Nasdaq also continues to post gains, although the S&P 500 continues to decline. For 2009, the Nasdaq is up 3.7 percent, while the S&P 500 is down 4.8 percent so far this year.

Of all the labs tracked in G-2's stock index, the top three to post gains was led by **Orchid Cellmark** (Princeton, N.J.), which is up 32 percent to \$1.11 per share for a market cap of \$32.64 million over the past four weeks for the week ended May 22. Following Orchid is **Genzyme** (Cambridge, Mass.), which is up 10 percent to \$58.37 per share for a market cap of \$15.99 billion. Rounding out these top gaining labs is **Bio-Reference Laboratories** (Elmwood Park, N.J.), up 8 percent to \$25.41 per share for a market cap of \$360.96 million.

For the week ended May 22, the top three labs posting the greatest losses was led by **Genomic Health** (Redwood City, Calif.), down 16 percent to \$18.35 per share for a market cap of \$544.92 million. Following Genomic Health is **Myriad Genetics** (Salt Lake City), which is down 14 percent to \$32.55 per share for a market cap of \$3.22 billion. Rounding out this group is **Monogram Biosciences** (South San Francisco, Calif.), which is down 9 percent to \$2.50 per share for a market cap of \$53.69 million. 🏢

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OIG Finds Improper Medicaid Spending on Lab Services

A recent report from the Department of Health and Human Services Office of Inspector General (OIG) charges that Medicaid programs in eight of 11 states examined by the agency spent \$1.3 million in fiscal years 2005 and 2006 on potentially improper payment for outpatient clinical diagnostic laboratory services for Medicare beneficiaries who also are entitled to some Medicaid benefits.

The OIG examined the 10 states with the highest Medicaid payments for all clinical diagnostic laboratory services for dual eligibles, including California, Florida, Illinois, Ohio, Mississippi, New Jersey, New York, North Carolina, Tennessee, Texas, as well as the state of Washington, which was included after discussions with the Centers for Medicare and Medicaid Services. Only Illinois, Mississippi, and New Jersey did not use Medicaid to improperly pay for lab tests during the years examined. The amounts of potentially improper payments found by the OIG ranged from \$5,482 in California to \$794,580 in Texas. For dual eligible beneficiaries, services that are covered by both Medicare and Medicaid are paid first by Medicare. Any remaining balance is covered by Medicaid up to the state's payment limit. 🏛️

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