Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

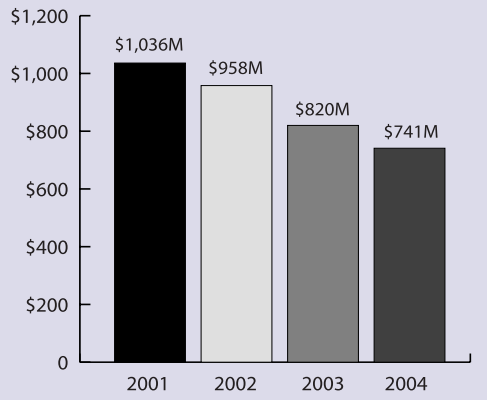
Abbott Diagnostics Plans Return To Growth

It's been more than a year since the FDA found Abbott Diagnostics to be back in compliance with the agency's quality system regulations, thus clearing the way for Abbott to begin introducing new immunoassays in the United States after a four-year dry spell. So far, regaining the hundreds of millions of dollars of market share that the company has lost over the past few years has proven to be difficult.

Last year, Abbott reported that revenue at its U.S. clinical diagnostic systems and reagents business fell 10% to $741 million, and the market share losses were even greater after adjusting for the acquisition of i-Stat in January 2004.

However, Christy Wistar, divisional vice president, U.S. marketing and commercial operations at Abbott Diagnostics, tells *DTTR* that hundreds of employees that had been focused on helping the company gain compliance with the FDA have been redeployed to research and development, client service, and sales and marketing positions. In addition, she says Abbott is aggressively expanding its test menu and increasing its presence at industry trade shows. "Customers are coming back. This year, we're looking to stabilize and grow," says Wistar. For more details, see *Inside the Diagnostics Industry*, pp. 5-9.

Abbott's Clinical Diagnostics Revenue* in USA



*excludes revenue from diabetes care (i.e., Medisense and TheraSense) Source: Abbott financial reports

Canon To Enter DNP Chip Market

Shareholders at the Japanese office equipment and camera maker Canon (Tokyo) have cleared the path for the company to develop and manufacture DNA chips for clinical diagnostics. On April 8, shareholders expanded Canon's articles of incorporation, which define the business areas in which the company operates, to include the production and sale of DNA chips. Canon has been researching DNA chip technology for several years, including developing chips for use in screening for colon cancer as part of a Japanese government-funded project. With the recent shareholders' approval, the company can now work toward the commercialization of products.

➥ *p. 2*

Canon is the latest of several Japanese firms that have taken an interest in the emerging DNA chip market. Apparently, these companies believe they can apply the mass production techniques they use in the beverage, consumer electronics, and printing industries to the large-scale production of DNA chips.

▲ **Canon to Enter DNA Chip Market,** *from page 1*

Canon is using the bubble-jet technology employed in its printers to produce DNA microarrays (aka chips), which are glass plates on which multiple rows of DNA solutions containing genes are placed. The solutions are placed onto the plate as dots 40 nanometers to 50 nanometers in diameter, using the printing technology. The company believes its method holds an advantage over current production techniques because it is cheaper and requires fewer production stages.

Earlier this year, *Nikkei Business* magazine had reported that Canon planned to spend up to 10 billion yen ($92 million) on the mass production of DNA chips, possibly in 2005, and that it wanted to reach 100 billion yen ($920 million) in sales in 2010. However, Richard Berger, a spokesman for Canon, says the company has not formally announced any investment plans or timing for commercialization.

In addition to Canon, several other Japanese companies are jumping into the fledgling DNA chip market. As odd as it may sound, these companies include the food and beverage producers Kirin Brewery and Takara Holdings Inc., the consumer-electronics firm Toshiba Corp., and Toppan Printing, the leading maker of color filters for flat-panel TVs.

Currently, the use of DNA chips is limited almost entirely to research and development by pharmaceutical and biotechnology companies. But late last year, Roche Diagnostics gained marketing clearance for its AmpliChip CYP450 microarray, marking the first-ever DNA chip approved by the FDA for kit sale to the clinical market. AmpliChip CYP450 analyzes a patient's Cytochrome P450 2D6 and 2C19 genotypes to look for variations that can influence drug metabolism. *DTTR* estimates that Roche is selling AmpliChip CYP450 to labs in the United States at a price of roughly $500 per chip.

AmpliChip CYP450 and related instrument systems are manufactured by Affymetrix (Santa Clara, CA), the world's largest DNA chip maker, under a nonexclusive agreement with Roche.

In the molecular diagnostics market, Affymetrix also has non-exclusive collaborations to develop clinical products with Arcturus Bioscience, Boston University Medical Center, Veridex LLC (owned by Johnson & Johnson), and BioMerieux.

Affymetrix's Partners in Molecular Diagnostics for the Clinical Market

Company	Type of Agreement
Arcturus Bioscience	Developing a platform to conduct gene-expression analysis on paraffin-embedded clinical biopsies
BioMerieux	Developing molecular diagnostics for bacteriology, virology, and breast cancer
Boston University Medical Center	Developing tools to screen for lung cancer
Roche Diagnostics	Developing DNA chips for a wide area of diseases
Veridex	Developing DNA chips for oncology

Source: Affymetrix

Biggest Commercial Labs Pay Less Than $4 Per Liquid Pap Test

In the last issue of *DTTR,* we published a summary of our exclusive Pap testing survey that showed the average lab pays $9.75 to Cytyc for its ThinPrep test and $7.91 for TriPath's SurePath. The survey was completed by 167 labs (115 hospitals, 31 independents, six pathology groups, six POLs, and nine other labs) around the country but did not include data from either Quest Diagnostics or LabCorp.

However, using data from our survey plus publicly available information from Cytyc and TriPath, we are able to estimate that Quest and LabCorp each pay well under $4 per test for mono-layer solution and supplies.

Meanwhile, our survey shows that smaller labs (15,000 and under Pap tests per year) pay an average of $10.09 per test for Cytyc's ThinPrep and $8.02 for TriPath's SurePath, while larger labs (15,000+ Pap tests) pay $9.48 for Cytyc and $7.87 for TriPath. This means that Quest and LabCorp are generating roughly an additional $5 of profit on every mono-layer test they perform when compared with local labs.

Obviously, it's large testing volume that gives Quest and LabCorp the leverage to negotiate such favorable pricing. For example, last year Quest alone represented 17%, or $67 million, of Cytyc's total revenue, while LabCorp represented 8%, or $31 million.

Average Prices Paid by Lab Size

	Cytyc	*TriPath*
Smaller labs (≤15,000 Paps)	$10.09	$8.02
Larger labs (>15,000 Paps)	9.48	7.87
Quest Diagnostics and LabCorp	<4.00	<4.00
Overall average for all labs	~7.00	~6.00

Source: *Washington G-2 Pap Testing Survey*, March 2005, and *DTTR* estimates

Will HPV Vaccines Supplant The Pap Testing Market?

Two major drug companies—GlaxoSmithKline and Merck—are each reporting progress toward developing a vaccine against human papillomavirus (HPV), the cause of cervical cancer. If progress continues apace, one or both companies could have a vaccine on the U.S. market within the next two years. Market introduction of one or more HPV vaccines is not likely to immediately reduce the number of cervical cancer tests performed each year. But over the long term, Pap testing volumes are likely to decline and/or the interval between testing is likely to lengthen because of vaccines, *DTTR* thinks.

Most recently, the British cancer journal *Lancet Oncology* published a study that showed dramatic results for Merck's experimental HPV vaccine (Gardasil), which targets the two strains of HPV (HPV types 16 and 18) that are most likely to cause cervical cancer as well as two other strains (types 6 and 11) that cause genital warts.

The trial involved 552 healthy women aged 16 to 23 who were recruited from Brazil, Europe and the United States. Led by Luisa Villa, Ph.D., researchers at the Ludwig Institute for Cancer Research in Sao Paulo, Brazil, assigned the vaccine randomly to 277 women; 275 others were given a placebo. The participants were then followed for 36 months.

The researchers reported that the "combined incidence of persistent infection or disease with HPV 6, 11, 16, or 18 fell by 90% in those assigned vaccine compared

with those assigned placebo." The vaccine was also 100% effective against precancerous cervical lesions and genital warts associated with the four HPV types. "If (larger) Phase III studies demonstrate the vaccine is as effective as this, I'm sure that it will change the history of cervical cancer," said Villa.

A vaccine (Cervarix) made by GlaxoSmithKline has also proved in a small trial reported last fall that it protects against HPV16 and HPV18. Both treatments are now in final-stage clinical studies designed to lead to approval for general clinical use in the United States and abroad.

But regulatory approval of any HPV vaccine would raise a number of social issues, according to Mark Stoler, M.D., a professor of pathology and gynecology at the University of Virginia Health System who was involved with the Merck study. HPV is sexually transmitted, so for a vaccination program to be effective, "parents would have to come around to the concept that their children need to be vaccinated for a sexually transmitted disease," he said.

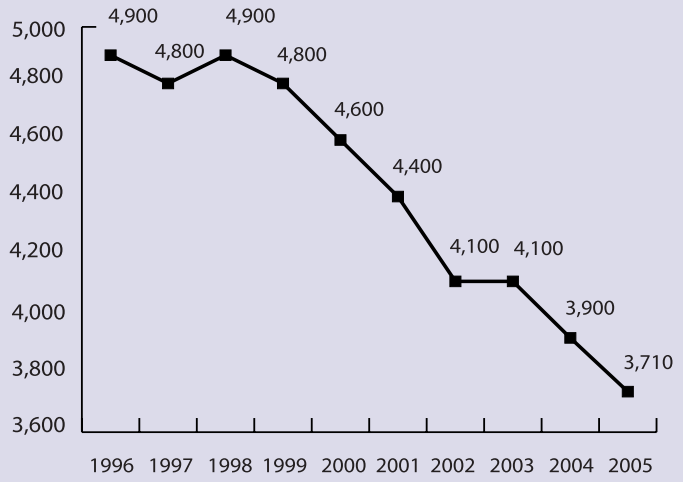
Alan Kaye, executive director of the National Cervical Cancer Coalition (Berkeley, CA), calls the potential market introduction of an HPV vaccine a "wonderful step forward" in the fight against cervical cancer. But he notes that a vaccine would only affect the first generation of young women who receive it, so every woman over the age of 15 would still need to get regular Pap tests for the rest of their lives.

Mono-Layer Pap Testing and the Reduction in Cervical Cancer Deaths

Separately, Kaye points out that the advent of mono-layer Pap testing may have something to do with the recent decline in the number of cervical cancer deaths in the United States. Throughout the 1990s, the number of women dying from cervical cancer remained at between 4,800 and 5,000 deaths per year in the United States, according to data from the National Cancer Institute.

However, beginning in the year 2000, the number of cervical cancer deaths began steadily declining (despite the growing and aging population). Kaye believes the cause for the decline has been the switch from traditional Pap smears to mono-layer preparation, which provides clearer slides for medical technologists and pathologists to review. "It's something that Cytyc and TriPath haven't advertised, but the numbers are there," says Kaye.

Number of Deaths from Cervical Cancer in United States



Source: National Cancer Institute

Correction: The last issue of *DTTR* contained an error in the last sentence of the second paragraph on page 6. In fact, MonoGen's new MonoPrep system is expected to have the ability to perform a broad base of molecular pathology testing because of a unique preservation solution that does not interfere with those tests.

Abbott Maps Out Plans For Getting Back On Top

Getting back into compliance with the FDA's quality system regulations has freed up tens of millions of dollars for Abbott Diagnostics to invest toward trying to regain the prominence it had five years ago in the U.S. diagnostics market. Its first year out from under the yoke of the FDA's penalties saw a continued deterioration in the company's share in the core clinical diagnostic systems and reagents market in the United States, although worldwide operating profits shot up 51% to $378 million. For details on how Abbott plans to restore growth to the top line, *DTTR* interviewed Christy Wistar, divisional vice president, U.S. marketing and commercial operations at Abbott Diagnostics. Here is an outline of what she told us:

Expanding the Immunoassay Test Menu

Wistar says that expanding the test menus for Abbott's AxSym and Architect immunoassay systems is a top priority. The FDA consent decree prevented Abbott from introducing new immunoassays to the U.S. market from January 2000 through December 2003. It also forced Abbott to suspend sales of three key anemia tests: vitamin B12, ferritin, and folate. And Abbott was forced to pay a 16% fine on sales of all other immunoassays manufactured at its Lake County, Illinois, diagnostics plant.

As a result, Abbott's immunoassay menu in the United States was frozen at 48 tests for AxSym and 11 tests for Architect. The inability to introduce new immunoassays gave Abbott's competitors a four-year advantage and emboldened several of them to make major financial commitments in the immunoassay market.

Abbott Diagnostics Key Data *($ millions)*

	2004	2003	2002	2001	2000	1999	5-Year CAGR*
Worldwide Diagnostics Revenue	$3,378	$3,040	$2,897	$2,929	$2,924	$3,010	2.3%
Immunochemistry	2,141	2,094	2,030	2,170	2,132	2,292	-1.4
Hematology and other diagnostics	446	404	373	304	357	343	5.4
Diabetes Care	791	542	494	455	435	375	16.1
Worldwide Diagnostic Operating Income	378	249	220	357	331	561	-7.6
							3-Year CAGR
USA Diagnostics Revenue	$1,119	$1,024	$1,163	$1,226	NA	NA	-3.0%
Clinical Diagnostic Systems and Reagents	741	820	958	1,036	NA	NA	-10.6
Diabetes Care	378	204	205	190	NA	NA	25.8

*Compound annual growth rate; does not include adjustments for acquisitions of Vysis, i-Stat, or TheraSense

Source: Abbott financial reports

But since the FDA's product ban was lifted in December 2003, Abbott has added a dozen tests to its AxSym menu, including free and total PSA, B-type Natriuretic Peptide (BNP), testosterone, and several thyroid and hepatitis tests. Over the past 18 months, Abbott has also added 10 immunoassays to its Architect menu, including the cancer tests CA 125 and CA 15-3, four tests for therapeutic drug monitoring, HBA1C, creatine kinase-MB (CK-MB), and alpha-fetoprotein (AFP).

Wistar says that immunoassays that will be added to the AxSym and Architect menus this year will be focused in the areas of cancer, thyroid, and metabolic tests. In addition, she expects vitamin B12, ferritin, and folate to get back on Abbott's immunoassay menus by year's end.

Abbott's market share losses in the U.S. are slowing down. In first-quarter 2005, Abbott's U.S. clinical diagnostic systems and reagents business fell 4% to $183 million—an improvement from double-digit losses from 2001 to 2004.

Is Abbott Cutting Price to Regain Market Share?

Abbott's annual report shows that worldwide pricing for the company's diagnostics business fell by an overall average of 1.2% in 2004. Abbott did not report details on pricing specific to the U.S. diagnostics market, and Wistar would not comment on the company's pricing strategies.

However, several lab managers and directors that participated in our *Quality Counts* survey (*see page 10*) reported that they were seeing significant pricing discounts from Abbott. "It appears that Abbott is being far more aggressive on price than I've seen in many years. My assumption is that this is a strategy to get back into the marketplace after they have been released from the FDA decree," said a lab executive from Oregon.

Meanwhile, a lab manager in California said: "Abbott is much more aggressive recently on pricing than in the past two years." And a lab manager in Missouri noted that his lab was getting "the lowest pricing possible for reagents" from Abbott.

Increasing Sales and Service Personnel

Since regaining compliance with the FDA, Abbott has significantly increased its number of workflow specialists, installation and integration personnel, and customer support and service staff, according to Wistar.

In addition, she says that Abbott has transformed its diagnostics business into a more global structure that uses best practices from around the world. For example, Abbott is now tracking analyzer system performance by serial number in the United States. Wistar says that anytime a system is found to have problems or glitches that exceed the norm, Abbott will make a service visit to correct the problem and make sure it doesn't happen again. This individual instrument tracking system was first used in Europe and greatly increased uptime, she says.

A Greater Presence at Industry Conferences

Wistar says that after laying low for a few years, Abbott is now increasing its presence at industry conferences. For example, she notes that after an absence of several years, Abbott had a booth at the CLMA/ASCP conference earlier this year in Chicago.

In addition, Abbott is stepping up its number of audio conferences with technical experts presenting on specific assays, especially in the areas of hepatitis, cardiac, and PSA testing. "We're trying to do a better job of communicating the extraordinary sensitivity our tests have, especially our troponin, estradiol, and TSH assays, so customers understand it's not just the size of a menu that counts," says Wistar.

Finally, she notes that Abbott will be featuring its new Architect i1000SR, a low-volume immunoassay system with rapid turnaround, at this summer's AACC annual meeting in Orlando. Abbott's new Architect c16000 for chemistry will also be on display, she adds.

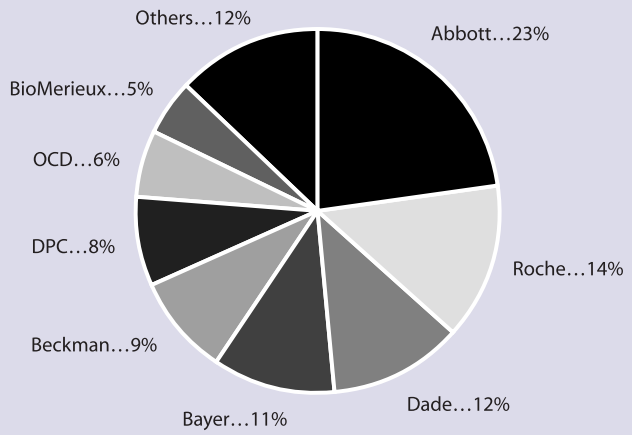
Rolling Out Two More Architour Trucks

Last year, Abbott introduced its mobile demonstration system, Architour, which utilizes a customized semi-trailer with the company's new Architect ci8200 immunochemistry system installed on board. Abbott's two Architour trucks made stops at more than 100 cities last year, giving demonstrations to roughly 3,500 lab directors and managers around the country. "Not all customers can make it to the AACC for a presentation, so we bring it to them," she notes. Wistar says that the Architour demonstrations have been so successful that Abbott is investing in two more trucks this year.

Immunoassay Market Share Trends

DTTR estimates that Abbott Diagnostics' market share in the worldwide immunoassay market (excluding the blood bank market) has fallen from 35% in 1999 to 23% in 2004. Competitors that have gained the most share over that time frame are Roche Diagnostics, Diagnostic Products Corp., and Bayer Diagnostics. A brief update on the latest news at three of Abbott's biggest competitors in the immunoassay market follows:

The $5.2 Billion Worldwide Immunoassay Market*, 2004



*Excludes blood banking, but includes protein plasma and TDM/DOA
Source: *DTTR* estimates

Roche Diagnostics' Elecsys immunoassay systems grew by 21% (adjusted for currency changes) to reach 882 million Swiss francs ($732 million) in worldwide revenue in 2004. Roche reports that it placed more than 1,600 Elecsys instruments last year to reach a total of approximately 11,500. Key immunoassays to be added to the U.S. menu this year include a vitamin D test and P1NP, a bone formation marker for treatment monitoring in osteoporosis.

Diagnostic Products Corp. (DPC) grew its Immulite product line by approximately 15% (adjusted for currency changes) to $405 million in worldwide revenue in 2004. For the year, the company shipped 977 Immulite instruments to reach a total of

more than 10,000. The FDA has prohibited DPC from introducing new tests to the U.S. market since February 2004, as a result of data integrity issues related to the company's Immulite Chagas test. Chief executive Michael Ziering expects the company to resolve its issues with the FDA by year's end. Tests the company is aiming to introduce in the United States following resolution include proBNP, ANA screen, and Epstein Barr.

Bayer Diagnostics reports that worldwide revenue from its Advia Centaur immunoassay system grew by 19% (adjusted for currency changes) to reach 441 million euros ($592 million) in 2004. Bayer currently has over 3,000 Centaurs installed worldwide, including about 1,200 in the United States. New test additions in 2005 will focus on infectious disease, especially hepatitis, according to a spokeswoman. She says the company also plans to launch its Advia Centaur CP for small- and mid-size labs by mid-year.

Worldwide Immunoassay Revenue* *($ millions)*

	2004	2003	2002	2001	3-Year CAGR
Abbott	$1,175	$1,260	$1,416	$1,541	-8.6%
Roche (Elecsys)	732	609	487	406	21.7
Dade Behring	650	590	537	488	10.0
Bayer (Advia Centaur)	568	498	438	334	19.4
Beckman Coulter	502	424	383	351	12.7
Diagnostic Products	405	338	277	230	20.7
OCD	300	280	265	245	7.0
BioMerieux	292	281	273	254	4.8
Others	695	660	630	600	5.8
Total	5,319	4,940	4,706	4,449	6.2

*Excludes blood banking, but includes protein plasma and TDM/DOA; Immunoassay revenue for Abbott, Dade, and OCD is estimated.

Source: *DTTR*

Beckman Coulter's worldwide immunodiagnostics business grew by 15% (adjusted for currency changes) last year to $502 million, including roughly $350 million from "pure" immunoassay business plus $150 million from rapid tests, point-of-care systems, and occult blood tests.

At a recent meeting with Wall Street analysts and investors in California, Beckman management reiterated its goal to reach $1 billion of immunodiagnostics revenue in the next five years. The greatest growth is expected to come from the immunoassay business, including anticipated growth of 25% to 30% in 2005.

The company says it's focusing on test menu expansion (both internally and through partnerships and licensing arrangements) and expects to introduce 7 to 10 new immunoassays this year. Tests currently under development include CMV IgG, CMV IgM, Anti-TPO, Intact PTH, DHEA-S, and Anti-Intrinsic Factor. In addition, the company plans to launch a new work cell (combination chemistry and immunoassay platform) toward the end of this year.

UBS Survey Sheds Light On Immunoassay Market Dynamics

As of year-end 2004, Abbott Diagnostics' immunoassay business had not yet stabilized, according to a survey of 338 hospital and reference labs conducted by UBS Investment Research in January. A total of 19 survey respondents reported that they had switched vendors in the past three months, and 53% (10/19) of these switched from Abbott, while 16% (3/19) switched from Roche, and 11% (2/19) switched from Bayer.

UBS Survey Respondents that Switched Immunoassay/Immunochemistry Vendors

Vendor	# of Respondents	% of Switchers
Abbott	10	53%
Bayer	2	11
Beckman Coulter	1	5
Dade Behring	1	5
Diagnostic Products	0	0
Olympus	0	0
Ortho-Clinical	0	0
Roche	3	16
Other	2	11
Total	19	100

Source: UBS Investment Research

"It is clear that Abbott has not yet begun to compete effectively for business, as this is the second consecutive quarter that Abbott has lost the most immunoassay customers, based on our surveys," said UBS analyst Benner Ulrich. [The previous survey in mid-2004 showed that 30% of switchers left Abbott.] Ulrich believes that Abbott may not begin winning back share until the latter part of this year.

Based on the survey results, the most important factor in influencing a customer's decision to switch is pricing, which was chosen by 21% (17/81) of respondents. This was closely followed by unique features on an instrument, such as automation (19% - 15/81), and dissatisfaction with service (16% - 13/81).

Reasons for Switching Immunoassay/ Immunochemistry Platforms

Reason for Switching	# of Respondents	% of % of Respondents
Pricing	17	21%
Unique features on new instrument	15	19
Dissatisfaction with service	13	16
Broader test menu on new instrument	11	14
Higher throughput on new instrument	10	12
Dissatisfaction with reliability of old instrument	7	9
Other	6	7
Other ancillary services	2	2
Total	81	100

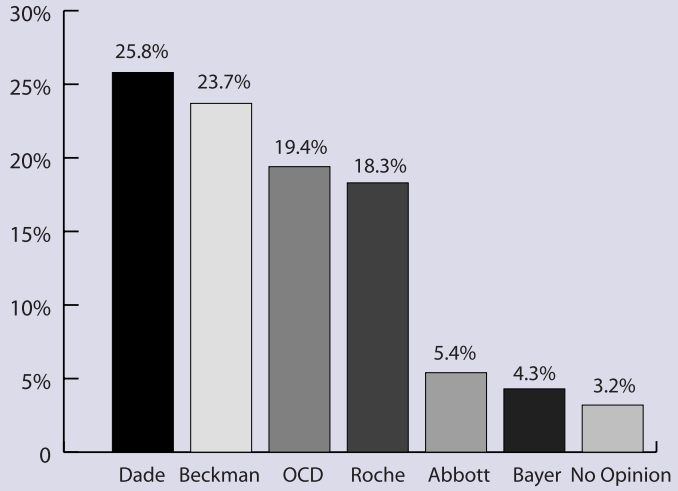
Source: UBS Investment Research

Meanwhile, the survey showed that labs are growing annual revenue by an average 6% to 9%, including 4% to 6% from volume and 2% to 3% from higher average prices. The key issues impacting the lab industry are: 1) workstation consolidation; and 2) growth in molecular diagnostics, according to survey respondents.

Smaller Labs Say Dade And Beckman Offer Best Value

Of the six biggest reagent vendors, Dade Behring offers the best value (i.e., service plus price), according to an independent survey of smaller labs conducted by Washington G-2 Reports. Dade was selected as "best value" by 26% of survey participants, followed by Beckman at 24%. In the middle were Ortho-Clinical Diagnostics (OCD), 19%; and Roche Diagnostics, 18%. Meanwhile, Abbott Diagnostics was selected by 5% and Bayer Diagnostics was picked by 4%.

Which major reagent vendor offers the best value (i.e., service plus price)?

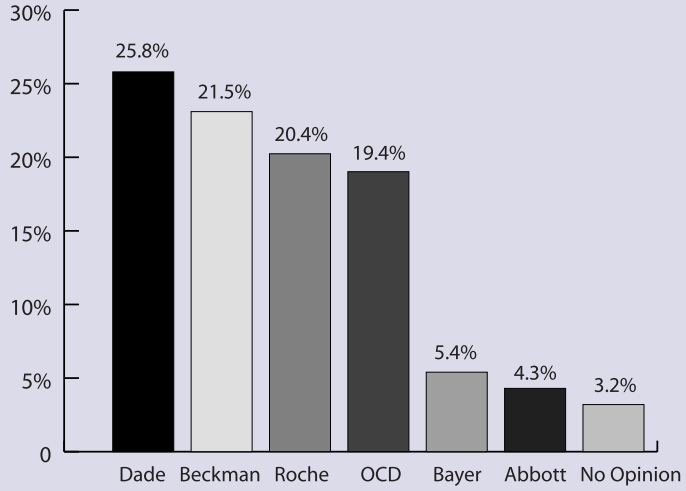


N=93 small labs. Source: *Quality Counts: Washington G-2 Reports' First National Reagent Vendor Quality Survey Report*

Quality Counts: Washington G-2 Reports' First National Reagent Vendor Quality Survey Report was sent out via e-mail on Oct. 26, 2004, to approximately 4,000 lab directors, managers, and supervisors throughout the nation. In all, 182 survey forms were completed and returned for a response rate of 5%. Among the survey respondents, 93 were from smaller labs (defined as less than 1 million tests per year).

Dade Behring was also cited by 26% of smaller-lab participants as being the major reagent vendor that was most responsive to answering questions and fixing problems. Beckman was cited by 22%, followed by Roche at 20% and OCD at 19%. Bayer was selected by 5% and Abbott by 4%.

Which major reagent vendor is the most responsive to answering questions and fixing problems?



N=93 small labs. Source: *Quality Counts: Washington G-2 Reports' First National Reagent Vendor Quality Survey Report*

Note: An overview of the survey results for all 182 respondents was published in the December 2004 issue of *Diagnostic Testing & Technology Report*. The complete *Quality Counts: Washington G-2 Reports' First National Reagent Vendor Quality Survey Report* is now available for sale at a price of only $425 for G-2 subscribers. Lab directors and managers can use this 65+ page hardcopy report to gain valuable insights from their peers to strengthen their decision-making process before signing their next long-term contract. Reagent vendors can use this information to better understand their strengths and weaknesses in the marketplace, as well as those of their competitors. For more information and an order form, go to *www.g2reports.com* and click on G-2 Products.

IVD Stocks Down 4% So Far In 2005

The cheapest IVD stocks today include Abaxis, which has a P/E ratio of 7, and Cholestech, which has a P/E of 12.

Twenty-five IVD stocks have fallen an unweighted average of 4% year-to-date through April 12. In comparison, the S&P 500 Index has fallen 2% year to date and the Nasdaq is down 8%.

Immucor (Norcross, GA), which specializes in instrument systems for blood banks, led all IVD companies with a stock price gain of 33% to $31.36 per share for a market value of $1.4 billion. The company recently reported that net income for the nine months ended Feb. 28, 2005 rose to $15.6 million from $9.15 million a year earlier; revenue was up 25% to $102.7 million. Immucor said profits improved because of price increases, higher sales of products using its Capture antibody-screening technology, and more efficient manufacturing because of facility consolidation.

Cholestech (Hayward, CA) is up 27% to $10.42 per share for a market value of $145 million. The company recently received FDA clearance for a high sensitivity C-Reactive Protein (hs-CRP) test to run on its portable LDX System and says the test will be on the market this summer of 2005.

Other IVD stocks that have booked double-digit stock gains include **Affymetrix**, up 23% to $45.11 per share for a market cap of $2.8 billion; **OraSure**, up 18% to $7.96 per share ($353 million); **Ventana**, up 14% to $36.61 per share ($1.3 billion); and **Gen-Probe**, up 11% to $50 per share ($2.5 billion).

Year-to-Date IVD Stock Review

Company (ticker)	12/31/04 Price	4/12/05 Price	YTD % Chg	P/E Ratio	Dividend Yield
Immucor (BLUD)	23.51	31.36	33%	78	N/A
Cholestech (CTEC)	8.20	10.42	27	12	N/A
Affymetrix (AFFX)	36.55	45.11	23	61	N/A
OraSure (OSUR)	6.72	7.96	18	N/A	N/A
Ventana (VMSI)	32.00	36.61	14	62	N/A
Gen-Probe (GPRO)	45.21	50.00	11	47	N/A
Johnson & Johnson (JNJ)	63.42	68.64	8	24	1.6%
Dade Behring (DADE)	56.00	58.98	5	34	N/A
Abbott Labs (ABT)	46.39	47.90	3	23	2.3
Becton Dickinson (BDX)	56.80	58.51	3	29	1.2%
Bayer (BAY)	33.98	34.26	1	31	1.6
Beckman Coulter (BEC)	66.99	67.33	1	21	0.8
Biosite (BSTE)	61.54	61.06	-1	19	N/A
Inverness Medical (IMA)	25.10	24.71	-2	N/A	N/A
Diagnostic Products (DP)	55.05	51.37	-7	25	0.5
Luminex (LMNX)	8.88	7.96	-10	N/A	N/A
Bio-Rad Labs (BIO)	57.37	50.05	-13	19	N/A
Meridian (VIVO)	17.41	15.08	-13	24	3.1
Cytyc (CYTC)	27.57	22.70	-18	36	N/A
Quidel (QDEL)	5.08	4.06	-20	N/A	N/A
TriPath Imaging (TPTH)	8.97	6.82	-24	N/A	N/A
Digene (DIGE)	26.15	19.80	-24	30	N/A
Exact Sciences (EXAS)	3.83	2.80	-27	N/A	N/A
Abaxis (ABAX)	14.49	8.65	-40	7	N/A
Third Wave (TWTI)	8.60	5.01	-42	N/A	N/A
Unweighted Avg.			-4		

NA=The company has reported a loss in the most recent four quarters or the P/E is 100 or more.
Source: *DTTR*

G-2 Insider

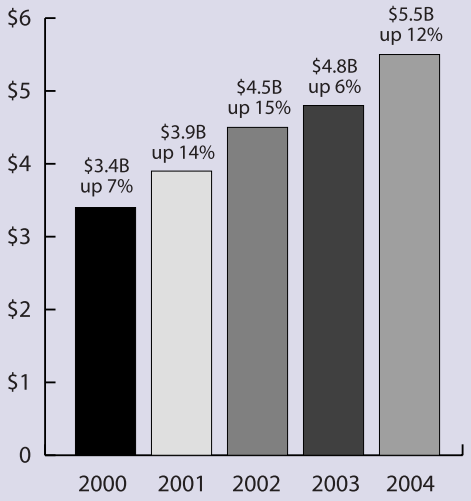
SMBG Testing Market Update: Manufacturers of self-monitoring blood glucose (SMBG) testing systems have little to fear from the FDA's recent approval of Symlin, an injection that helps diabetics using insulin gain better control of their blood sugar, particularly after a meal, according to David Kliff, publisher of the online newsletter Diabetic Investor. The pending clearance of exenatide, another drug for glucose control, will not significantly impact the glucose testing market either, he says.

These drugs, both developed by Amylin Pharmaceuticals, represents the first new drugs for the treatment of diabetes since insulin was introduced in the 1920s. Kliff says that while market introduction of Symlin and exenatide could have a small negative impact on the volume of blood glucose testing, but says a more revolutionary change will come when the first continuous blood glucose monitoring and insulin delivery systems come to market. These devices will wirelessly transmit the user's glucose level to insulin pumps for automatic insulin delivery.

He notes that all of the major SMBG vendors (i.e., Roche, JNJ, Bayer, and Abbott) are developing continuous systems as well as Medtronic, Becton Dickinson, and some 20 smaller medical technology companies. The sensor technology employed in continuous systems could completely disrupt traditional glucose testing and "that day is getting close," according to Kliff.

Meanwhile, financial results from the top manufacturers show that growth in the SMBG testing business rebounded to 12% last year to reach a worldwide market of $5.5 billion (*see graph*).

Annual Growth Rates for Worldwide SMBG Market



Source: *DTTR* estimates

Company References

Abbott Labs 847-937-6100
Bayer Diagnostics 914-631-8000
Beckman Coulter 714-871-4848
Cytyc Corp. 978-263-8000
Dade Behring 847-267-5300
Diabetic Investor 800-783-3712
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