Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

WASHINGTON G-2 REPORTS

Established 1979

Correlogic's OvaCheck May Need An FDA Review

The nations two largest commercial labs, Quest Diagnostics and LabCorp, have been gearing up to launch homebrew versions of OvaCheck, a highly anticipated test for ovarian cancer that uses technology licensed from Correlogic Systems (Bethesda, MD). But it looks like the test may need premarket approval from the FDA before it can be marketed for clinical use.

In a February 18 letter, Steven Gutman, M.D., director of the FDA's Office of In Vitro Diagnostics, requested a meeting with Correlogic's president Peter Levine to "discuss the nature and appropriate regulatory status of your technology and the least burdensome ways that Correlogic Systems may fulfill any premarket review requirements that may apply." Gutman's attention was probably raised after a 1,600-word article on OvaCheck appeared in the *New York Times* on February 2.

The Correlogic test uses a proprietary software program to analyze blood protein patterns generated by mass spectrometry. Quest and LabCorp are each now in the validation process and had hoped to soon begin marketing the test as a screen for the eight million women in the United States who are at increased risk for ovarian cancer. Levine tells *DTTR* that his company is now in the process of setting up a meeting with the FDA. See page 12 for more details.

Cytyc To Shell Out $325 Million In Cash For Novacept

Cytyc Corp. (Boxborough, MA), whose last effort to diversify (ductal lavage testing) has turned out to be a disappointment, is now spending $325 million to purchase Novacept (Palo Alto, CA), a privately held company that sells a medical device for treating excessive menstrual bleeding. The purchase price is equal to 8.5 times Novacept's revenue of $38.4 million for 2003 and 6.8 times its estimated revenue of $47.5 million for this year. The acquisition is expected to close by the end of March, and Cytyc will use $75 million of its available cash plus a $250 million loan to pay for it.

Each year, approximately 2.5 million women in the United States seek treatment for excessive menstrual bleeding. Current treatment options include hormone therapy, hysterectomy, and endometrial ablation, which involves removing the lining of a woman's uterus. Novacept's NovaSure System is one of five "second generation" endometrial ablation systems now sold in the United States.

➠ *p. 2*

Cytyc is the market share leader in mono-layer testing, where its main competitor is TriPath. The acquisition of Novacept brings Cytyc into a new market where its top competitor will be Johnson & Johnson.

▲ **Cytyc To Shell Out $325 Million,** *from page 1*

Last year an estimated 230,000 endometrial ablation procedures were performed in the United States, and Cytyc believes this market will grow to 400,000 procedures by 2008, driven by new minimally invasive endometrial ablation technologies such as Novacept's NovaSure product.

The first-generation endometrial ablation techniques were introduced in the 1980s and are still practiced by many gynecologists today. The 25-minute procedure involves using a hysteroscope (a thin, fiber-optic tube for viewing) with a "rollerball" attachment that delivers electrical heat to destroy tissue in the uterus. The procedure requires a high level of surgical skill and pretreatment with hormonal drugs.

In 1997, the FDA approved Johnson & Johnson's ThermaChoice, the first non-hysteroscopic ablation device to treat excessive uterine bleeding. Since then, four other second-generation devices have been cleared by the FDA, including Novacept's NovaSure product.

The second-generation systems are generally easier and quicker for physicians to perform. The NovaSure system, which does not require hormonal pretreatment, includes two components. One is a disposable unit with a soft wire mesh that is inserted into the uterus. A hand-held computer sends radio-frequency energy to the mesh, causing heat that burns the uterine lining. The computer continually senses the energy and resistance and shuts off automatically once the uterine lining has been burned off, preventing damage to the uterine muscle or surrounding organs. The four-minute procedure is typically done at an outpatient surgery center.

On a March 1 conference call, Patrick Sullivan, chief executive of Cytyc, described the NovaSure product as "best in class" and noted that payer reimbursement is well established. In fact, CMS increased the facility reimbursement rate to $1,535 from $983 effective Jan. 1, 2004. Physicians are reimbursed approximately $350 to $400 per procedure, according to Sullivan. NovaSure's disposable units sell for roughly $850 each, and the hand-held controller, which can be used multiple times, sells for about $13,000.

Sullivan cited the cross-selling opportunities for ThinPrep and NovaSure. He said that Cytyc will soon add 20 people to its current 100-person sales team, which will continue to focus on OB/GYN offices; Novacept's 60-person sales force will be expanded to 80 people who will focus on hospitals and outpatient surgery centers.

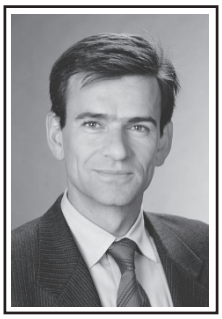
Sullivan thinks the worldwide revenue opportunity for NovaSure could exceed $1 billion per year. "We believe this acquisition will put us on a strong and diversified financial growth trajectory on both the top and bottom line and will position us to become the worldwide leader in providing innovative products for women's health," he said.

For the Skeptics...

Cytyc's last move to diversify by acquisition has thus far turned out to be an expensive disappointment. In November 2001, the company acquired ProDuct Health for $176 million in cash and stock. At the time of the acquisition, Cytyc had believed that ProDuct's ductal lavage testing method for determining predisposition to breast cancer would contribute $40 million per year in revenue by 2003. But these expectations have not panned out. In fact, *DTTR* estimates that ductal lavage generated less than $5 million in revenue for Cytyc in 2003. The company says it has now turned its focus toward developing more clinical studies for the test.

What's Next For Roche Diagnostics?

Over the past 12 months, the world's largest IVD manufacturer, Roche Diagnostics (Basel, Switzerland), has seen tremendous highs and forgettable lows. Among the highs: Roche lengthened its lead in the glucose monitoring market with a 10% sales gain (excluding Disetronic acquisition and adjusted for currency fluctuations) to 2.7 billion Swiss franc (US $2.1 billion). Among the lows: A major push into the emerging DNA chip market was stymied last summer when the FDA questioned the ASR classification of Roche's new AmpliChip CYP450 microarray.



Martin Madaus

For perspective on where Roche stands on these issues plus some insight into the company's strategic focus for the coming 12 months, *DTTR* recently interviewed Martin Madaus, head of Roche's U.S. diagnostic operations based in Indianapolis. Here's a summary:

DTTR: What's the current status of your AmpliChip CYP450 microarray product for drug metabolism?
Madaus: We're currently offering it on a research-use-only basis. Three different clinical studies for the product are under way, focused on its use in prescribing anti-psychotic drugs. We're also working to improve the throughput and automation for the product.

Our decision on whether to market the product for clinical use will depend on the outcome of the clinical studies. The regulatory process for bringing this novel device to the market is also in flux. We're currently in debate with the FDA on how this product should be regulated.

Note: Roche began marketing its AmpliChip CYP450 to U.S laboratories in July 2003 on an analyte-specific-reagent (ASR) basis. Shortly thereafter, the FDA notified Roche that it had questions about the ASR status of the product. And in November 2003, the FDA ruled that AmpliChip CYP450 could not be commercially distributed for clinical testing without a premarket determination.

DTTR: Have you completed your acquisition of Igen?
Madaus: Yes. We closed the transaction in mid-February. We had always promised our customers that we would solve this problem [the licensing dispute] and we did. The important thing was that all through the dispute we never interrupted our development efforts for new immunoassays. Key product launches scheduled for 2004 include a P1NP bone formation marker for treatment monitoring of osteoporosis, and S100 for treatment monitoring of skin cancer. Another focus is on developing new cardiac markers.

DTTR: What are your plans for competing in the HPV testing market?
Madaus: In January we launched an Amplicor product that detects for 13 high-risk HPV genotypes that laboratories need to validate themselves. We've completed 12 different clinical studies on the test so far, and we're doing more studies right now. We anticipate submitting an application to the FDA sometime next year.

We're also developing a linear array HPV product that can detect and identify 37 HPV types. Right now, it's available for research use, and we're waiting to see what

the customer demand will be before introducing a clinical test. Also in development is an HPV test for use on our Cobas TaqMan Analyzer, which will couple HPV detection with Roche's real-time PCR technology on an automated platform.

DTTR: What's the demand been like for your NT-proBNP test?
Madaus: It's been our biggest product launch in at least the past 10 years. The key advantage is that we can sell it to our existing base of Elecsys customers, which lets us get into some very big health systems. Our pricing is very comparable to that of the competition. [As of year-end 2003, Roche had approximately 10,000 Elecsys platforms placed worldwide, including 900 in the United States.]

DTTR: Is the slowdown in the glucose monitoring business permanent?
Madaus: Yes. The question is now if the new growth rate will be 3% like last year or 6% to 7%. Two factors have contributed to the slowdown. Long-acting insulin and oral treatments are cutting into the frequency of testing and there's been some impact from the weak economy. This is being offset somewhat by continued growth in the diabetic population.

The good news for Roche is that it achieved double-digit growth last year, while sales declined at Abbott, Bayer, and Lifescan. Our Accu-Chek Compact has been doing very well, even outperforming the market-share gains made by TheraSense. Our top initiative is addressing manufacturing concerns from the FDA, so we can get our insulin pumps back on the U.S. market.

DTTR: What's your outlook for the competition between hospitals, commercial labs, and POLs?
Madaus: I see no major market share shifts, although hospital outreach programs seem to be gaining some momentum with their customized service and local nature. I also see more esoteric testing moving into mainstream labs. Smaller labs are acquiring more sophisticated systems. As for physician office labs, they're a good place to do testing, but the regulatory requirements are too onerous and the reimbursement is poor.

Top-Selling Product Lines at Roche Diagnostics

Product Line	Market Segment	Worldwide Sales 2003 ($ millions)[1]	Growth[2] 2003 vs. 2002
Accu-Chek[3]	Diabetes management	1,907	13%
Hitachi/Integra[4]	Clinical chemistry	822	2%
Elecsys	Immunochemistry	564	25%
Amplicor	Molecular diagnostics	506	10%
Ampli/TaqScreen	Blood screening	165	47%
CoaguChek	Coagulation	109	20%

[1]based on exchange ratio of 1 Swiss franc=$0.72 USD [2]growth is adjusted for currency fluctuations
[3]includes Glucotrend meters [4]excluding homogeneous immunoassays

Source: *DTTR* from Roche financials

New Cancer Diagnostics Discussed At Wachovia Securities Conference

New technologies were the focus at Wachovia Securities Second Annual Cancer Diagnostics Conference in New York City, February 24. **Daniel Chan, Ph.D.**, director of the Biomarker Discovery Center at Johns Hopkins Medical Institutions (Baltimore, MD), noted the need for new blood tests to detect cancer (*see table below*). He observed that the total PSA test for prostate cancer is considered the best test available for any cancer, yet a person could have a normal result and still have a 25% chance of having cancer. Highlights of some of the other presentations follow:

FDA Approval of Erbitux to Spur EGFR Testing

Richard Bender, M.D., medical director for hematology/oncology at Quest Diagnostics, told the conference audience that he expects an "enormous volume" of initial lab testing related to the introduction of Erbitux. He noted that there are approximately 165,000 new colorectal cancer cases diagnosed in the United States each year and another 250,000 patients already under therapy. Bender estimated that Erbitux will be considered for 50,000 to 100,000 patients within the next 12 months.

On February 12, the FDA approved Erbitux, a colon cancer drug made by ImClone Systems and distributed by Bristol-Myers Squibb. In related news, DakoCytomation (Carpinteria, CA) has received FDA clearance for the use of its EGFR pharmDx kit as an aid in identifying colorectal cancer patients eligible for treatment with Erbitux.

DakoCytomation's EGFR pharmDx kit identifies epidermal growth factor receptor (EGFR) in tissue sections. EGFR is a protein expressed in a variety of cancers, including colorectal, lung, breast, pancreatic, bladder, prostate, kidney, and head and neck.

Leading Cancer Cases and Deaths in United States, 2004

Type	*New Cases*	*Deaths*	*Lab Tests**
Lung	173,770	160,440	None
Colon	106,370	56,730	CEA
Breast	217,440	40,580	CA15-3/CA27.29
Pancreas	31,860	31,270	CA19-19
Prostate	230,110	29,900	PSA (total, complex, free)
Non-Hodgkin Lymphoma	54,370	19,410	None
Ovary	25,580	16,090	CA 125
Liver	18,920	14,270	AFP (alpha-fetoprotein)
Esophagus	14,250	13,300	None
Urinary	60,240	12,710	None
Brain	18,400	12,690	None
Kidney	35,710	12,480	None

*excluding tissue examinations by pathologists

Source: American Cancer Society estimates and *DTTR*

DakoCytomation submitted a premarket approval application to the FDA for EGFR pharmDx in September 2003 in parallel with ImClone's Erbitux submission. The approved EGFR pharmDx indication is based on the results of a pivotal Erbitux clinical trial that utilized the kit to aid in finding patients whose tumors expressed EGFR.

Erbitux is a monoclonal antibody designed to bind specifically to EGFR and block certain growth factors from binding and signaling the cell to promote tumor cell growth, survival, and progression. Erbitux is shot into a vein and costs $10,000 per month (i.e., one dose per week at $2,400 per dose). Medicare reimbursement to laboratories and pathologists for EGFR testing is capped at $84.38 under CPT code 88342 (immunocytochemistry).

Separately, **Christopher Gleason**, chief executive at Ventana Medical Systems (Tucson, AZ), said his company is working with Bristol Myers to develop an EGFR test for Erbitux that it aims to have on the U.S. market in April in an ASR format. "We're assuming this market will be pretty big," said Gleason.

New Technologies for Colorectal Cancer Screening

A panel of experts discussed new technologies for colorectal cancer testing. **Steven Itzkowitz, M.D.**, a gastroenterology professor at the Mount Sinai School of Medicine (New York City) who has served as an advisor to Exact Sciences (Marlborough, MA), said that there are too many recommended options for colorectal cancer screening, including fecal occult blood tests (FOBTs), flexible sigmoidoscopy, and colonoscopies. Over time, he expects FOBTs and flexible sigmoidoscopy to "fade away" and be replaced by greater use of DNA-based testing methods and virtual colonoscopies.

He compared the first-generation DNA-based test [a.k.a., Exact's PreGen-Plus] to the model-T Ford and said the test would improve over time. A key question that needs to be answered is how often should DNA-based testing for colorectal cancer be repeated, noted Itzkowitz.

Richard Wender, M.D., chair of the department of family medicine at Jefferson Medical College (Philadelphia) and an advisor to Enterix (Falmouth, ME), said that Enterix's immunochemical FOBT offers several advantages over traditional guaiac-based FOBTs, including the need for two specimens (not three) and sample collection, using a long-handled brush (not a spatula). Wender believes the cost of DNA-based methods ($795 list price) is too expensive for widespread adoption by primary care physicians.

Sidney Winawer, M.D., a professor of medicine at Memorial Sloan-Kettering Cancer Center (New York City) and an advisor to Exact Sciences, said that immunochemical FOBTs could be the "next-generation" screen for colorectal cancer, and DNA-based testing may become the third generation. He noted that immunochemical FOBTs are already in wide use in Japan and Australia.

Expert Opinion on HPV Testing

The conference featured a panel discussion on cervical cancer that focused on HPV testing. **Douglas Clark, M.D.**, director of the division of cytopathology, department of pathology at Johns Hopkins Medical Institutions (Baltimore), said that HPV testing for cervical cancer will grow in importance over the next few years. He noted that while several drug companies were working on vaccines for HPV, market introduction was not likely within the next five years.

Clark said that extending the interval for cervical cancer screening from once per year with the traditional Pap test to once every three years for the DNA Pap

(*i.e.*, traditional Pap plus HPV test) was risky. He pointed out that if a woman misses a DNA Pap appointment, then she could wind up going without being tested for four or five years.

Christopher Crum, M.D., director of women's and perinatal pathology at Brigham and Women's Hospital (Boston), noted that most women do not develop serious abnormalities despite HPV infection. This can result in a large number of referrals for needless colposcopies and biopsies.

He said there was a need for manufacturers to develop HPV tests that can not only detect multiple high-risk HPV types, but also identify specific types. He noted that Digene (Gaithersburg, MD) is working on a next-generation HPV test (Hybrid-Capture 3) that will provide improved HPV typing capabilities, as are Access Genetics (Minneapolis, MN) and Roche.

Crum also noted that Ventana's Inform HPV test may be an answer for identifying those women with HPV that definitely have cervical cancer. Inform is a tissue-based test that allows pathologists to see if an HPV infection is actually inside the cells and therefore more serious. Ventana sells the test in ASR format for $80; Medicare reimbursement is $110 under CPT code 88365.

Carolyn Runowicz, M.D., notes that key questions regarding the frequency of the new DNA Pap still need to be answered, such as, "Will consumers want an HPV and Pap test every year once direct-to-consumer advertising happens?"

Carolyn Runowicz, M.D., director, UConn Comprehensive Cancer Center (Farmington, CT), said her biggest fear is that a large number of women with a negative Pap test that are HPV positive will have their cervixes needless removed. She agreed that there is a strong need for an HPV test that identifies specific types and stratifies the risk of cervical cancer for each type. Because of the high false positive rate associated with HPV testing, Runowicz suggested that it might make more sense to reverse the current protocol and screen with an HPV test first and reflex positives to a Pap test for confirmation.

The Competition between Cytyc and TriPath

Patrick Sullivan, chief executive of Cytyc Corp. (Boxborough, MA), said his company's ThinPrep (average selling price: $7) deserves a premium price to TriPath's SurePrep (ASP: $4.50) because it has been cleared for HPV testing straight out of the vial. In addition, he noted that Cytyc's recently cleared ThinPrep Imaging System provides labs with reimbursement of $37 per test versus $28.31 for manual thin-layer and $14.76 per traditional pap smear.

Cytyc is charging labs an additional $7.50 per automated ThinPrep test and is aiming to have automated imaging systems in place at 127 labs by year's end. Sullivan said that Cytyc had invested roughly $50 million to develop its ThinPrep Imaging System.

Paul Sohmer, M.D., chief executive of TriPath Imaging (Burlington, NC), said it was "bad form" for Cytyc to sell its products to labs based on the reimbursement. Over the long term, he anticipates that reimbursement for thin-layer testing techniques will decline. "You can't make the assumption that these prices will last indefinitely. Payers will push prices as volume continues to increase. The pressure will build," said Sohmer. He noted that neither LabCorp nor Quest has made a decision regarding which automated system they'll use (*i.e.*, TriPath's or Cytyc's).

FDA Suspends Review Of Pending Tests For DPC

The FDA action is a big setback given that DPC has always taken pride in its wide menu.

Diagnostic Products Corp. (DPC-Los Angeles) says that the FDA has suspended review of pending and future applications from the company because of issues raised by the agency under its Application Integrity Policy (also known as the Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Policy). In a March 3 press release, DPC said that this action was taken based on the FDA's inspectional findings related to DPC's Chagas diagnostic test application.

According to February 24 letter from the FDA to DPC—a copy of which was obtained by *DTTR*—the FDA's inspection and disclosures made by DPC identified the following list of system-wide and data integrity problems:

- ❑ Failure to report known false negative and false positive study results.
- ❑ Failure to report adverse reproducibility (precision) studies from four clinical sites.
- ❑ Misrepresentation of data in that DPC assigned clinical symptoms and conditions to patients without access to patient records.
- ❑ Failure to follow company Standard Operating Procedures.
- ❑ Failure to monitor clinical studies.
- ❑ Failure to maintain accurate and complete records.
- ❑ Failure to obtain and maintain Financial Disclosure Forms for any of the [clinical study] investigators.

DPC chief executive Michael Ziering said in the press release: "We have initiated a process to identify and correct the causes of these issues. Our understanding is that a reasonable time for resolution of these types of issues is approximately 12 months."

James Brill, spokesman for DPC, tells *DTTR* that although tests that DPC has already received clearance for are not part of the FDA's action, DPC will still probably go back and review its data collection processes for those tests as well.

Brill notes that the issue will not affect the company's new instrument, the Immulite 2500, or the 74 assays that run on it, which were approved by the FDA late last year. DPC plans to launch the Immulite 2500 within the next few weeks. Its main benefit is rapid turnaround time (15-20 minutes) for cardiac tests. In addition, Brill says that the FDA action does not affect the introduction of tests that are sold outside of the United States, which accounted for 71% of 2003 sales of $381.4 million.

However, the FDA action may delay DPC's plans to introduce a BNP test in the United States. The company recently announced that it had obtained a nonexclusive license from Roche Diagnostics to develop an immunoassay using Roche's congestive heart failure marker, NT-proBNP. Development of this test was a high priority for DPC, and the company had hoped to submit an application to the FDA by year's end. Other tests in development that may be delayed include D-dimer and an autoimmune screening test.

Biosite Gets License For Cleveland Clinic's MPO Marker

Biosite (San Diego) has announced that the Cleveland Clinic has granted it certain diagnostic rights to myeloperoxidase (MPO), a marker of inflammation in the walls of coronary arteries that can signal a person's risk for heart disease or

heart attack (*see DTTR, March 2004, pp. 1-2*). Biosite will have exclusive diagnostic rights for point-of-care testing and semi-exclusive rights for automated testing. Biosite will pay undisclosed milestone payments and royalties for any commercialized products. Stan Hazen, M.D., Ph.D., head of the preventive cardiology section at Cleveland Clinic and head researcher behind the MPO marker, says that an FDA-cleared MPO test for screening patients that visit hospitals with chest pain could be on the market by mid-2005.

Separately, Biosite says that it has entered into a license and collaboration agreement with DMI BioSciences (DMI—Englewood, CO) under which Biosite will development a test for cysteinylated albumin (cys-albumin), a biomarker that is elevated in blood when a patient is undergoing ischemia. Ischemia is an imbalance between oxygen supply and demand that leads to oxygen deficiency in tissues such as the heart. The presence of ischemia can be a sign of angina or even heart attack. Under the terms of the agreement, Biosite has obtained certain exclusive and semi-exclusive diagnostic rights to the biomarker and will pay DMI milestones and royalties for any diagnostic products that Biosite commercializes.

The Mini-Boom In New Laboratory Construction

Within the past six months, there has been a mini-boom in new lab construction across the United States by both hospital systems and commercial laboratories. The wave in new lab openings is creating numerous opportunities for IVD vendors of all sizes to win significant contracts for lab equipment and long-term reagent agreements.

Among the largest projects is the construction of a new 150,000 square-foot core laboratory that will consolidate testing from three hospitals that are part of **Clarian Health Partners** (Indianapolis), including Methodist, Indiana University, and Riley hospitals. Clarian is investing $65 million in the new facility, which is expected to open in early 2006, according to John Eble, M.D., chief pathologist and chairman of the pathology and laboratory medicine departments at Clarian. He says that Clarian has already begun reviewing its vendor options for the installation of a new automation system for chemistry/immunoassay that will at the minimum cover front-end tasks.

Quest Diagnostics (Teterboro, NJ) opened a new 110,000 square-foot facility in Houston in February that consolidated three existing labs it had in the area. Anatomic pathology and flow cytometry are among the new services it added in conjunction with the opening. Quest is also building a new lab facility in Los Angeles that will consolidate two existing labs in the area. The new facility will be well over 100,000 square feet and is expected to be completed sometime next year.

TriCore Reference Laboratories (Albuquerque, NM) opened up a new 95,000 square-foot corporate headquarters and core laboratory in downtown Albuquerque earlier this year. The new facility is being used to consolidate lab testing from three of TriCore's existing labs in Albuquerque. TriCore is an independent lab formed by the University of New Mexico, Presbyterian Hospital, and St. Vincent's Hospital in 1998. Russell Duke, Ph.D., chief executive, says TriCore is standardizing its

coagulation on a platform from Diagnostica Stago; hematology is being standardized on Beckman Coulter systems. TriCore is now preparing to send out an RFP for an automated chemistry/immunoassay system, notes Duke.

Specialty Laboratories (Santa Monica, CA) is consolidating four laboratory and office buildings now in Santa Monica into a new 198,000 square-foot, three-story facility in Valencia (30 miles north of Santa Monica). The move is scheduled to begin at mid-year.

LabCorp (Burlington, NC) recently renewed and expanded a long-term contract to manage three laboratories for Swedish Health System in Seattle. The arrangement covers approximately two million billable tests per year performed at Swedish Medical Center's First Hill, Ballard, and Swedish Providence campuses, according to Brian Kuske, vice president for ambulatory and ancillary services at Swedish. He says that LabCorp is contemplating the construction of a new lab facility in Seattle so that it can consolidate the testing provided to the three hospitals.

LabOne (Lenexa, KS) recently acquired Alliance Laboratory Services (ALS) from Health Alliance of Greater Cincinnati for $42.4 million. ALS is a core laboratory with 600 employees that generates approximately $40 million per year in revenue from outreach services and reference testing to six Health Alliance hospitals. Mike Asselta, chief operating officer at LabOne, says his company plans to spend $20 million to build a new lab in the Cincinnati area that will be a minimum of 80,000 square feet.

Among three smaller lab companies that have recently opened new labs is **Southern Diagnostics** (Birmingham, AL), a new independent lab company that opened up a 15,000 square-foot facility last summer. The company was founded by its president, Steven Boyd, a former sales executive at Dynacare (now part of LabCorp). Among the platforms placed in the new lab are an immunoassay analyzer from DPC and a chemistry analyzer from Olympus.

ChromaVision (San Juan Capistrano, CA) recently announced that it would begin providing technical pathology services to clients using its automated cell-imaging systems. The company has hired three executives formerly with Impath (New York City) to run its new laboratory, which will initially be located at its current research lab facility. A spokesman says ChromaVision will seek to expand its menu of lab services and may seek to move into a new and larger lab facility.

Finally, **NeoGenomics** (Fort Myers, FL), a small independent reference lab, opened up a new 5,200 square-foot lab in Fort Myers earlier this year.

10 New Laboratory Facilities

Hospital/Lab Company	New Facility Location	Square Footage	Opening Date
ChromaVision	San Juan Capistrano, CA	NA	March 2004
Clarian Health Partners	Indianapolis, IN	150,000	early 2006
LabCorp	Seattle, WA	NA	2005-2008*
LabOne	Cincinnati area	80,000+	late 2004
NeoGenomics	Fort Myers, FL	5,200	Feb. 2004
Quest Diagnostics	Houston, TX	110,000	Feb. 2004
Quest Diagnostics	Los Angeles, CA	100,000+	2005
Southern Diagnostics	Birmingham, AL	15,000	Aug. 2003
Specialty Laboratories	Valencia, CA	198,000	mid 2004
TriCore Reference Labs	Albuquerque, NM	95,000	Jan. 2004

*Plans have not been finalized

Source: *DTTR*

IVD Stocks Up 7% Year To Date; Cytyc Leads With 53% Gain

Twenty-five publicly traded IVD stocks are up an unweighted average of 7% year to date through March 3, 2004. This compares with a year-to-date gain of 4% for the S&P 500 Index and a 2% gain for the Nasdaq.

Cytyc has jumped 53% to $21.11 per share, largely on news that it's acquiring the medical device maker Novacept (*see pp. 1-2*). Cytyc now has a market capitalization of $2.3 billion, which is equal to 7.6 times its 2003 revenue of $303 million and 30 times its net income of $76 million.

The next biggest gainer is **Gen-Probe** (San Diego), which has climbed 44% to $35.37 per share. The company now has a market cap of $1.8 billion, a valuation that is 8.6 times its 2003 revenue of $207 million and 49 times its net income of $35 million.

Other IVD stocks that have logged big gains include reagent-maker **Apogent** (Portsmouth, NH), which is up 21% to $27.99 per share, and **Becton Dickinson** (Franklin Lakes, NJ), which is up 19% to $48.92 per share.

IVD Stock Review

	Div. Yield	P/E Ratio	12/31/03 Price	3/4/04 Price	YTD % Chg
Abaxis (ABAX)	0.0	na	$18.09	$18.60	3%
Abbott (ABT)	2.2%	20	46.60	43.63	-6%
Apogent (AOT)	0.0	na	23.04	27.99	21%
Bayer (BAY)	3.5%	na	29.41	28.91	-2%
Beckman Coulter (BEC)	0.8%	19	50.83	54.12	6%
Becton Dickinson (BDX)	0.9%	22	41.14	48.92	19%
Bio-Rad (BIO)	0.0	18	57.67	57.71	0%
Biosite (BSTE)	0.0	21	28.95	31.50	9%
Cholestech (CTEC)	0.0	24	7.64	8.29	9%
Cytyc (CYTC)	0.0	30	13.84	21.11	53%
Dade Behring (DADE)	0.0	37	35.74	41.65	17%
Diagnostic Products (DP)	0.5%	22	45.91	45.40	-1%
Digene (DIGE)	0.0	na	40.10	38.60	-4%
Exact Sciences (EXAS)	0.0	na	10.12	7.76	-23%
Gen-Probe (GPRO)	0.0	49	24.57	35.37	44%
Immucor (BLUD)	0.0	29	20.39	20.67	1%
Inverness Medical (IMA)	0.0	29	21.78	21.45	-2%
Johnson & Johnson (JNJ)	1.8%	20	51.66	53.03	3%
Luminex (LMNX)	0.0	na	9.38	9.14	-3%
Meridian (VIVO)	3.3%	23	10.44	11.37	9%
OraSure (OSUR)	0.0	na	7.96	9.00	13%
Quidel (QDEL)	0.0	36	10.77	8.70	-19%
Third Wave Tech (WAVE)	0.0	na	4.45	4.79	8%
TriPath Imaging (TPTH)	0.0	na	7.80	8.65	11%
Ventana (VMSI)	0.0	61	$39.40	$42.50	8%
Unweighted Average					7%

Na=The company reported a loss in the most recent four quarters or the P/E is 100 or more

Source: *DTTR* from Bloomberg

G-2 Insider

If all had gone as planned, Quest and LabCorp would soon begin marketing a profitable new test, OvaCheck, that offered substantial clinical improvement over the current standard (CA-125) for screening for ovarian cancer. With recent articles in the *New York Times*, *Wall Street Journal*, and numerous trade publications, the medical and financial communities were each eagerly awaiting the new age of protein pattern analysis. On a conference call with analysts earlier this year, LabCorp chairman Tom Mac Mahon stated plans for a launch on April 1. But now that the FDA is inquiring about the test, executives at Correlogic, Quest, and LabCorp have given up trying to predict when rollout might begin.

Correlogic's president Peter Levine says his company has invested millions of dollars into the novel technology behind OvaCheck. And at a recent conference, Richard Bender, M.D., medical director for hematology/oncology at Quest, said that Quest was testing 1,000 specimens to validate the sensitivity and specificity of OvaCheck. "This is the most meticulous validation I've ever been involved with," said Bender.

But *DTTR* notes that Roche Diagnostics was in a similar position when it began marketing its novel CYP450 AmpliChip product last summer. A quick letter from the FDA dashed hopes that this test could bypass FDA scrutiny. Roche is now working to complete clinical studies and wrangling with the FDA on the appropriate regulatory path for reintroducing AmpliChip for clinical use.

Levine says that OvaCheck is a different animal than Roche's AmpliChip and believes that labs should be allowed to offer homebrew versions. But he adds, "It's the FDA's role to ask questions, and it's our job to answer them." The key question is: What exactly is Correlogic selling to Quest and LabCorp—intellectual property, a software program, reagents, lab equipment? The answer to this question will determine whether OvaCheck goes on the market this year or several years from now.

Company References

Biosite 858-455-4808
Correlogic 301-214-4030
Cytyc Corp. 978-263-8000
DPC 310-645-8200
LabCorp 336-584-5171
Quest Diagnostics 201-393-5000
TriCore Reference Labs 505-224-7999
TriPath 336-222-9707
Ventana 520-887-2155

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